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(Acts whose publication is obligatory)

## COMMISSION DIRECTIVE 96/77/EC

of 2 December 1996

laying down specific purity criteria on food additives other than colours and sweeteners

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption<sup>(1)</sup>, as amended by European Parliament and Council Directive 94/34/EC<sup>(2)</sup>, and in particular Article 3 (3) (a) thereof,

After consulting the Scientific Committee for Food,

Whereas it is necessary to establish purity criteria for all additives other than colours and sweeteners mentioned in European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners<sup>(3)</sup>;

Whereas it is necessary to replace the purity criteria set out in Council Directive 65/66/EEC of 26 January 1965 laying down specific criteria of purity for preservatives authorized for use in foodstuffs intended for human consumption<sup>(4)</sup>, as last amended by Directive 86/604/EEC<sup>(5)</sup>;

Whereas it is necessary to replace the purity criteria set out in Council Directive 78/664/EEC of 25 July 1978 laying down specific criteria of purity for antioxidants which may be used in foodstuffs intended for

human consumption<sup>(6)</sup>, as amended by Directive 82/712/EEC<sup>(7)</sup>;

Whereas Directives 65/66/EEC and 78/664/EEC should be repealed accordingly;

Whereas it is necessary to take into account the specifications and analytical techniques for additives as set out in the *Codex Alimentarius* as drafted by the Joint FAO/WHO Expert Committee on Food Additives (Jecfa);

Whereas food additives, if prepared by production methods or starting materials significantly different from those included in the evaluation of the Scientific Committee for Food, or if different from those mentioned in this Directive, should be submitted for evaluation by the Scientific Committee for Food for the purposes of a full evaluation with emphasis on the purity criteria;

Whereas, the measures provided for in this Directive are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

The purity criteria referred to in Article 3 (3) (a) of Directive 89/107/EEC for food additives other than colours and sweeteners, as mentioned in Directive 95/2/EC, are set out in the Annex hereto.

*Article 2*

Directives 65/66/EEC and 78/664/EEC are hereby repealed.

<sup>(1)</sup> OJ No L 40, 11. 2. 1989, p. 27.

<sup>(2)</sup> OJ No L 237, 10. 9. 1994, p. 1.

<sup>(3)</sup> OJ No L 61, 18. 3. 1995, p. 1.

<sup>(4)</sup> OJ No 22, 9. 2. 1965, p. 373.

<sup>(5)</sup> OJ No L 352, 13. 12. 1986, p. 45.

<sup>(6)</sup> OJ No L 223, 14. 8. 1978, p. 30.

<sup>(7)</sup> OJ No L 297, 23. 10. 1982, p. 31.

*Article 3*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1997. They shall immediately inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

2. Products put on the market or labelled before 1 July 1997 which do not comply with this Directive may be marketed until stocks are exhausted.

*Article 4*

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Communities*.

*Article 5*

This Directive is addressed to the Member States.

Done at Brussels, 2 December 1996.

*For the Commission*

Martin BANGEMANN

*Member of the Commission*

## ANNEX

## E 200 SORBIC ACID

## Definition

<i>Chemical name</i>	Sorbic acid Trans, trans-2,4-hexadienoic acid
<b>Einecs</b>	203-768-7
<i>Chemical formula</i>	C <sub>6</sub> H <sub>8</sub> O <sub>2</sub>
<i>Molecular weight</i>	112,12
<i>Assay</i>	Content not less than 99 % on the anhydrous basis
<i>Description</i>	Colourless needles or white free flowing powder, having a slight characteristic odour and showing no change in colour after heating for 90 minutes at 105 °C

## Identification

A. Melting range	Between 133 °C and 135 °C, after vacuum drying for four hours in a sulphuric acid desiccator
B. Spectrometry	An isopropanol solution (1 in 4 000 000) shows absorbance maximum at 254 ± 2 nm
C. Positive test for double bonds	
D. Sublimation point	80 °C

## Purity

Water content	Not more than 0,5 % (Karl Fischer method)
Sulphated ash	Not more than 0,2 %
Aldehydes	Not more than 0,1 % (as formaldehyde)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 202 POTASSIUM SORBATE

## Definition

<i>Chemical name</i>	Potassium sorbate Potassium (E,E)-2,4-hexadienoate Potassium salt of trans, trans 2,4-hexadienoic acid
<b>Einecs</b>	246-376-1
<i>Chemical formula</i>	C <sub>6</sub> H <sub>7</sub> O <sub>2</sub> K
<i>Molecular weight</i>	150,22
<i>Assay</i>	Content not less than 99 % on the dried basis
<i>Description</i>	White crystalline powder showing no change in colour after heating for 90 minutes at 105 °C

**Identification**

- A. Melting range of sorbic acid isolated by acidification and not recrystallized 133°C to 135°C after vacuum drying in a sulphuric acid desiccator
- B. Positive tests for potassium and for double bonds

**Purity**

Loss on drying	Not more than 1,0 % (105°C, 3h)
Acidity or alkalinity	Not more than about 1,0 % (as sorbic acid or K <sub>2</sub> CO <sub>3</sub> )
Aldehydes	Not more than 0,1 %, calculated as formaldehyde
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 203 CALCIUM SORBATE****Definition**

<i>Chemical name</i>	Calcium sorbate Calcium salts of trans, trans-2,4-hexadienoic acid
<b>Einecs</b>	231-321-6
<i>Chemical formula</i>	C <sub>12</sub> H <sub>14</sub> O <sub>4</sub> Ca
<i>Molecular weight</i>	262,32
<i>Assay</i>	Content not less than 98 % on the dried basis
<i>Description</i>	Fine white crystalline powder not showing any change in colour after heating at 105°C for 90 minutes

**Identification**

- A. Melting range of sorbic acid isolated by acidification and not recrystallized 133°C to 135°C after vacuum drying in a sulphuric acid desiccator
- B. Positive tests for calcium and for double bonds

**Purity**

Loss on drying	Not more than 2,0 %, determined by vacuum drying for four hours in a sulphuric acid desiccator
Aldehydes	Not more than 0,1 % (as formaldehyde)
Fluoride	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 210 BENZOIC ACID

## Definition

<i>Chemical name</i>	Benzoic acid Benzenecarboxylic acid Phenylcarboxylic acid
<i>Einecs</i>	200-618-2
<i>Chemical formula</i>	C <sub>7</sub> H <sub>6</sub> O <sub>2</sub>
<i>Molecular weight</i>	122,12
<i>Assay</i>	Content not less than 99,5 % on the anhydrous basis
<i>Description</i>	White crystalline powder

## Identification

A. Melting range	121,5°C to 123,5°C
B. Positive sublimation test and test for benzoate	

## Purity

Loss on drying	Not more than 0,5 % after drying for three hours over sulphuric acid
pH	About 4 (solution in water)
Sulphated ash	Not more than 0,05 %
Chlorinated organic compounds	Not more than 0,07 % expressed as chloride corresponding to 0,3 % expressed as monochlorobenzoic acid
Readily oxidizable substances	Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N KMnO <sub>4</sub> in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N KMnO <sub>4</sub> to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required
Readily carbonizable substances	A cold solution of 0,5 g of benzoic acid in 5 ml of 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC <sup>(1)</sup> , 0,3 ml of ferric chloride TSC <sup>(2)</sup> , 0,1 ml of copper sulphate TSC <sup>(3)</sup> and 4,4 ml of water
Polycyclic acids	On fractional acidification of a neutralized solution of benzoic acid, the first precipitate must not have a different melting point from that of the benzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

<sup>(1)</sup> Cobalt chloride TSC: dissolve approximately 65 g of cobalt chloride CoCl<sub>2</sub>·6H<sub>2</sub>O in a sufficient quantity of a mixture of 25 ml hydrochloric acid and 975 ml of water to give a total volume of 1 litre. Place exactly 5 ml of this solution in a round-bottomed flask containing 250 ml of iodine solution, add 5 ml of 3 % hydrogen peroxide, then 15 ml of a 20 % solution of sodium hydroxide. Boil for 10 minutes, allow to cool, add 2 g of potassium iodide and 20 ml of 25 % sulphuric acid. After the precipitate is completely dissolved, titrate the liberated iodine with sodium thiosulphate (0,1 N) in the presence of starch TS<sup>(\*)</sup>. 1 ml of sodium thiosulphate (0,1 N) corresponds to 23,80 mg of CoCl<sub>2</sub>·6H<sub>2</sub>O. Adjust final volume of solution by the addition of a sufficient quantity of the hydrochloric acid/water mixture to give a solution containing 59,5 mg of CoCl<sub>2</sub>·6H<sub>2</sub>O per ml.

<sup>(2)</sup> Ferric chloride TSC: dissolve approximately 55 g of ferric chloride in a sufficient quantity of a mixture of 25 ml of hydrochloric acid and 975 ml of water to give a total volume of 1 litre. Place 10 ml of this solution in a round-bottomed flask containing 250 ml of iodine solution, add 15 ml of water and 3 g of potassium iodide; leave the mixture to stand for 15 minutes. Dilute with 100 ml of water then titrate the liberated iodine with sodium thiosulphate (0,1 N) in the presence of starch TS<sup>(\*)</sup>. 1 ml of sodium thiosulphate (0,1 N) corresponds to 27,03 mg of FeCl<sub>3</sub>·6H<sub>2</sub>O. Adjust final volume of solution by the addition of a sufficient quantity of the hydrochloric acid/water to give a solution containing 45,0 mg of FeCl<sub>3</sub>·6H<sub>2</sub>O per ml.

<sup>(3)</sup> Copper sulphate TSC: dissolve approximately 65 g of copper sulphate CuSO<sub>4</sub>·5H<sub>2</sub>O in a sufficient quantity of a mixture of 25 ml of hydrochloric acid and 975 ml of water to give a total volume of 1 litre. Place 10 ml of this solution in a round-bottomed flask containing 250 ml of iodine solution, add 40 ml of water, 4 ml of acetic acid and 3 g of potassium iodide. Titrate the liberated iodine with sodium thiosulphate (0,1 N) in the presence of starch TS<sup>(\*)</sup>. 1 ml of sodium thiosulphate (0,1 N) corresponds to 24,97 mg of CuSO<sub>4</sub>·5H<sub>2</sub>O. Adjust final volume of solution by the addition of a sufficient quantity of the hydrochloric acid/water mixture to give a solution containing 62,4 mg of CuSO<sub>4</sub>·5H<sub>2</sub>O per ml.

<sup>(\*)</sup> Starch TS: triturate 0,5 g starch (potato starch, maize starch of soluble starch) with 5 ml of water; to the resulting paste add a sufficient quantity of water to give a total volume of 100 ml, stirring all the time. Boil for a few minutes, allow to cool, filter. The starch must be freshly prepared.

## E 211 SODIUM BENZOATE

**Definition***Chemical name*

Sodium benzoate  
Sodium salt of benzenecarboxylic acid  
Sodium salt of phenylcarboxylic acid

*Einecs*

208-534-8

*Chemical formula* $C_7H_5O_2Na$ *Molecular weight*

144,11

*Assay*Not less than 99 % of  $C_7H_5O_2Na$ , after drying at 105 °C for four hours*Description*

A white, almost odourless, crystalline powder or granules

**Identification**

## A. Solubility

Freely soluble in water, sparingly soluble in ethanol

## B. Melting range for benzoic acid

Melting range of benzoic acid isolated by acidification and not recrystallized 121,5 °C to 123,5 °C, after drying in a sulphuric acid desiccator

## C. Positive tests for benzoate and for sodium

**Purity**

## Loss on drying

Not more than 1,5 % after drying at 105 °C for four hours

## Readily oxidizable substances

Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N  $KMnO_4$  in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N  $KMnO_4$  to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required

## Polycyclic acids

On fractional acidification of a (neutralized) solution of sodium benzoate, the first precipitate must not have a different melting range from that of benzoic acid

## Chlorinated organic compounds

Not more than 0,06 % expressed as chloride, corresponding to 0,25 % expressed as monochlorobenzoic acid

## Degree of acidity or alkalinity

Neutralization of 1 g of sodium benzoate, in the presence of phenolphthalein, must not require more than 0,25 ml of 0,1 N NaOH or 0,1 N HCl

## Arsenic

Not more than 3 mg/kg

## Lead

Not more than 5 mg/kg

## Mercury

Not more than 1 mg/kg

## Heavy metals (as Pb)

Not more than 10 mg/kg

## E 212 POTASSIUM BENZOATE

**Definition***Chemical name*

Potassium benzoate  
Potassium salt of benzenecarboxylic acid  
Potassium salt of phenylcarboxylic acid

*Einecs*

209-481-3

*Chemical formula* $C_7H_5KO_2 \cdot 3H_2O$

<i>Molecular weight</i>	214,27
<i>Assay</i>	Content not less than 99 % C <sub>7</sub> H <sub>5</sub> O <sub>2</sub> K after drying at 105 °C to constant weight
<i>Description</i>	White crystalline powder
<b>Identification</b>	
A. Melting range of benzoic acid isolated by acidification and not recrystallized 121,5 °C to 123,5 °C, after vacuum drying in a sulphuric acid desiccator	
B. Positive tests for benzoate and for potassium	
<b>Purity</b>	
Loss on drying	Not more than 26,5 %, determined by drying at 105 °C
Chlorinated organic compounds	Not more than 0,06 % expressed as chloride, corresponding to 0,25 % expressed as monochlorobenzoic acid
Readily oxidizable substances	Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N KMnO <sub>4</sub> in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N KMnO <sub>4</sub> to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required
Readily carbonizable substances	A cold solution of 0,5 g of benzoic acid in 5 ml 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC, 0,3 ml of ferric chloride TSC, 0,1 ml of copper sulphate TSC and 4,4 ml of water
Polycyclic acids	On fractional acidification of a (neutralized) solution of potassium benzoate, the first precipitate must not have a different melting range from that of benzoic acid
Degree of acidity or alkalinity	Neutralization of 1 g of potassium benzoate, in the presence of phenolphthalein, must not require more than 0,25 ml of 0,1 N NaOH or 0,1 N HCl
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 213 CALCIUM BENZOATE**

<b>Synonyms</b>	Monocalcium benzoate
<b>Definition</b>	
<i>Chemical name</i>	Calcium benzoate Calcium dibenzoate

<b>Einecs</b>	218-235-4
<i>Chemical formula</i>	Anhydrous: $C_{14}H_{10}O_4Ca$ Monohydrate: $C_{14}H_{10}O_4Ca \cdot H_2O$ Trihydrate: $C_{14}H_{10}O_4CA \cdot 3H_2O$
<i>Molecular weight</i>	Anhydrous: 282,31 Monohydrate: 300,32 Trihydrate: 336,36
<i>Assay</i>	Content not less than 99 % after drying at 105 °C
<i>Description</i>	White or colourless crystals, or white powder
<b>Identification</b>	
A. Melting range of benzoic acid isolated by acidification and not recrystallized 121,5 °C to 123,5 °C, after vacuum drying in a sulphuric acid desiccator	
B. Positive tests for benzoate and for calcium	
<b>Purity</b>	
Loss on drying	Not more than 17,5 % determined by drying at 105 °C to constant weight
Water insoluble matter	Not more than 0,3 %
Chlorinated organic compounds	Not more than 0,06 % expressed as chloride, corresponding to 0,25 % expressed as monochlorobenzoic acids
Readily oxidizable substances	Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N $KMnO_4$ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N $KMnO_4$ to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required
Readily carbonizable substances	Cold solution of 0,5 g of benzoic acid in 5 ml of 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC, 0,3 ml of ferric chloride TSC, 0,1 ml of copper sulphate TSC and 4,4 ml of water
Polycyclic acids	On fractional acidification of a (neutralized) solution of calcium benzoate, the first precipitate must not be a different melting range from that of benzoic acid
Degree of acidity or alkalinity	Neutralization of 1 g of calcium benzoate, in the presence of phenolphthalein, must not require more than 0,25 ml of 0,1 N NaOH or 0,1 N HCl
Fluoride	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 214 ETHYL *p*-HYDROXYBENZOATE**

<b>Synonyms</b>	Ethylparaben Ethyl <i>p</i> -oxybenzoate
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**Definition**

<i>Chemical name</i>	Ethyl- <i>p</i> -hydroxybenzoate Ethyl ester of <i>p</i> -hydroxybenzoic acid
<b>Einecs</b>	204-399-4
<i>Chemical formula</i>	C <sub>9</sub> H <sub>10</sub> O <sub>3</sub>
<i>Molecular weight</i>	166,8
<i>Assay</i>	Content not less than 99,5 % after drying for two hours at 80 °C
<i>Description</i>	Almost odourless, small, colourless crystals or a white, crystalline powder

**Identification**

A. Melting range	115 °C to 118 °C
B. Positive test for <i>p</i> -hydroxybenzoate	Melting range of <i>p</i> -hydroxybenzoic acid isolated by acidification and not recrystallized: 213 °C to 217 °C, after vacuum drying in a sulphuric acid desiccator
C. Positive test for alcohol	

**Purity**

Loss on drying	Not more than 0,5 % after drying for two hours at 80 °C
Sulphated ash	Not more than 0,05 %
<i>p</i> -Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 215 SODIUM ETHYL *p*-HYDROXYBENZOATE****Definition**

<i>Chemical name</i>	Sodium ethyl <i>p</i> -hydroxybenzoate Sodium compound of the ethyl ester of <i>p</i> -hydroxybenzoic acid
<b>Einecs</b>	252-487-6
<i>Chemical formula</i>	C <sub>9</sub> H <sub>9</sub> O <sub>3</sub> Na
<i>Molecular weight</i>	188,8
<i>Assay</i>	Content of ethylester of <i>p</i> -hydroxybenzoic acid not less than 83 % on the anhydrous basis
<i>Description</i>	White, crystalline hygroscopic powder

**Identification**

A. Melting range	115 °C to 118 °C, after vacuum drying in a sulphuric acid desiccator
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B. Positive test for <i>p</i> -hydroxybenzoate	Melting range of <i>p</i> -hydroxybenzoic acid derived from the sample is 213°C to 217°C
C. Positive test for sodium	
D. pH of a 0,1% aqueous solution must be between 9,9 and 10,3	
<b>Purity</b>	
Loss on drying	Not more than 5 %, determined by vacuum drying in a sulphuric acid desiccator
Sulphated ash	37 to 39 %
<i>p</i> -Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 216 PROPYL *p*-HYDROXYBENZOATE**

<b>Synonyms</b>	Propylparaben Propyl <i>p</i> -oxybenzoate
<b>Definition</b>	
<i>Chemical name</i>	Propyl <i>p</i> -hydroxybenzoate n-Propyl <i>p</i> -hydroxybenzoic acid
<b>Einecs</b>	202-307-7
<i>Chemical formula</i>	C <sub>10</sub> H <sub>12</sub> O <sub>3</sub>
<i>Molecular weight</i>	180,21
<i>Assay</i>	Content not less than 99,5 % after drying for two hours at 80°C
<i>Description</i>	Almost odourless, small, colourless crystals or a white, crystalline powder
<b>Identification</b>	
A. Melting range	95°C to 97°C after drying for two hours at 80°C
B. Positive test for <i>p</i> -hydroxybenzoate	Melting range of <i>p</i> -hydroxybenzoic acid derived from the sample is 213°C to 217°C
<b>Purity</b>	
Loss on drying	Not more than 0,5 % after drying for two hours at 80°C
Sulphated ash	Not more than 0,05 %
<i>p</i> -Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 217 SODIUM PROPYL *p*-HYDROXYBENZOATE

## Definition

<i>Chemical name</i>	Sodium n-propyl <i>p</i> -hydroxybenzoate Sodium compound of the n-propylester of <i>p</i> -hydroxybenzoic acid
Einecs	252-488-1
<i>Chemical formula</i>	C <sub>10</sub> H <sub>11</sub> O <sub>3</sub> Na
<i>Molecular weight</i>	202,21
Assay	Content of the propyl ester of <i>p</i> -hydroxybenzoic acid not less than 85 % on the anhydrous basis
<i>Description</i>	White, or almost white, crystalline hygroscopic powder

## Identification

- A. Melting range of ester isolated by acidification and not recrystallized: 94°C to 97°C, after vacuum drying in a sulphuric acid desiccator
- B. Positive test for sodium
- C. pH of a 0,1% aqueous solution must be between 9,8 and 10,2

## Purity

Loss on drying	Not more than 5 %, determined by vacuum drying in a sulphuric acid desiccator
Sulphated ash	34 to 36 %
<i>p</i> -Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 218 METHYL *p*-HYDROXYBENZOATE

## Synonyms

Methylparaben  
Methyl-*p*-oxybenzoate

## Definition

<i>Chemical name</i>	Methyl <i>p</i> -hydroxybenzoate Methyl ester of <i>p</i> -hydroxybenzoic acid
Einecs	243-171-5
<i>Chemical formula</i>	C <sub>9</sub> H <sub>8</sub> O <sub>3</sub>

<i>Molecular weight</i>	152,15
<i>Assay</i>	Content not less than 99 % after drying for two hours at 80 °C
<i>Description</i>	Almost odourless, small colourless crystals or white crystalline powder
<b>Identification</b>	
A. Melting range	125 °C to 128 °C
B. Positive test for <i>p</i> -hydroxybenzoate	Melting range of <i>p</i> -hydroxybenzoic acid derived from the sample is 213 °C to 217 °C after drying for two hours at 80 °C
<b>Purity</b>	
Loss on drying	Not more than 0,5 %, after drying for two hours at 80 °C
Sulphated ash	Not more than 0,05 %
<i>p</i> -Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 219 SODIUM METHYL *p*-HYDROXYBENZOATE**

<b>Definition</b>	
<i>Chemical name</i>	Sodium methyl <i>p</i> -hydroxybenzoate Sodium compound of the methylester of <i>p</i> -hydroxybenzoic acid
<i>Chemical formula</i>	C <sub>8</sub> H <sub>7</sub> O <sub>3</sub> Na
<i>Molecular weight</i>	174,15
<i>Assay</i>	Content not less than 99,5 % on the anhydrous basis
<i>Description</i>	White, hygroscopic powder
<b>Identification</b>	
A. The white precipitate formed by acidifying with hydrochloric acid a 10 % (w/v) aqueous solution of the sodium derivative of methyl <i>p</i> -hydroxybenzoate (using litmus paper as indicator) shall, when washed with water and dried at 80 °C for two hours, have a melting range of 125 °C to 128 °C	
B. Positive test for sodium	
C. pH of a 0,1 % solution in carbon dioxide free water, not less than 9,7 and not more than 10,3	

**Purity**

Water content	Not more than 5 % (Karl Fischer method)
Sulphated ash	40 % to 44,5 % on the anhydrous basis
<i>p</i> -Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 220 SULPHUR DIOXIDE****Definition**

<i>Chemical name</i>	Sulphur dioxide Sulphurous acid anhydride
<b>Einecs</b>	231-195-2
<i>Chemical formula</i>	SO <sub>2</sub>
<i>Molecular weight</i>	64,07
<i>Assay</i>	Content not less than 99 %
<i>Description</i>	Colourless, non-flammable gas with strong pungent suffocating odour

**Identification**

A. Positive test for sulphurous substances

**Purity**

Water content	Not more than 0,05 %
Non-volatile residue	Not more than 0,01 %
Sulphur trioxide	Not more than 0,1 %
Selenium	Not more than 10 mg/kg
Other gases not normally present in the air	No trace
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 221 SODIUM SULPHITE

## Definition

<i>Chemical name</i>	Sodium sulphite (anhydrous or heptahydrate)
<i>Einecs</i>	231-821-4
<i>Chemical formula</i>	Anhydrous: $\text{Na}_2\text{SO}_3$ Heptahydrate: $\text{Na}_2\text{SO}_3 \cdot 7\text{H}_2\text{O}$
<i>Molecular weight</i>	Anhydrous: 126,04 Heptahydrate: 252,16
<i>Assay</i>	Anhydrous: Not less than 95 % of $\text{Na}_2\text{SO}_3$ and not less than 48 % of $\text{SO}_2$ Heptahydrate: Not less than 48 % of $\text{Na}_2\text{SO}_3$ and not less than 24 % of $\text{SO}_2$
<i>Description</i>	White crystalline powder or colourless crystals

## Identification

- A. Positive tests for sulphite and for sodium
- B. pH of a 10 % solution (anhydrous) or a 20 % solution (heptahydrate) between 8,5 and 11,5

## Purity

Thiosulphate	Not more than 0,1 % based on the $\text{SO}_2$ content
Iron	Not more than 50 mg/kg based on the $\text{SO}_2$ content
Selenium	Not more than 10 mg/kg based on the $\text{SO}_2$ content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 222 SODIUM BISULPHITE

## Definition

<i>Chemical name</i>	Sodium bisulphite Sodium hydrogen sulphite
<i>Einecs</i>	231-921-4
<i>Chemical formula</i>	$\text{NaHSO}_3$ in aqueous solution
<i>Molecular weight</i>	104,06
<i>Assay</i>	Content not less than 32 % w/w $\text{NaHSO}_3$
<i>Description</i>	A clear, colourless to yellow solution

**Identification**

- A. Positive tests for sulphite and for sodium
- B. pH of a 10 % aqueous solution between 2,5 and 5,5

**Purity**

Iron	Not more than 50 mg/kg of Na <sub>2</sub> SO <sub>3</sub> based on the SO <sub>2</sub> content
Selenium	Not more than 10 mg/kg based on the SO <sub>2</sub> content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 223 SODIUM METABISULPHITE****Synonyms**

Pyrosulphite  
Sodium pyrosulphite

**Definition**

*Chemical name* Sodium disulphite  
Disodium pentaoxidisulphate

*Einecs* 231-673-0

*Chemical formula* Na<sub>2</sub>S<sub>2</sub>O<sub>5</sub>

*Molecular weight* 190,11

*Assay* Content not less than 95 % Na<sub>2</sub>S<sub>2</sub>O<sub>5</sub> and not less than 64 % of SO<sub>2</sub>

*Description* White crystals or crystalline powder

**Identification**

- A. Positive tests for sulphite and for sodium
- B. pH of a 10 % aqueous solution between 4,0 and 5,5

**Purity**

Thiosulphate	Not more than 0,1 % based on the SO <sub>2</sub> content
Iron	Not more than 50 mg/kg based on the SO <sub>2</sub> content
Selenium	Not more than 10 mg/kg based on the SO <sub>2</sub> content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
<b>E 224 POTASSIUM METABISULPHITE</b>	
<b>Synonyms</b>	Potassium pyrosulphite
<b>Definition</b>	
<i>Chemical name</i>	Potassium disulphite Potassium pentaoxo disulphate
<b>Einecs</b>	240-795-3
<i>Chemical formula</i>	$K_2S_2O_5$
<i>Molecular weight</i>	222,33
<i>Assay</i>	Content not less than 90 % of $K_2S_2O_5$ and not less than 51,8 % of $SO_2$ , the remainder being composed almost entirely of potassium sulphate
<i>Description</i>	Colourless crystals or white crystalline powder
<b>Identification</b>	
A. Positive tests for sulphite and for potassium	
<b>Purity</b>	
Thiosulphate	Not more than 0,1 % based on the $SO_2$ content
Iron	Not more than 50 mg/kg based on the $SO_2$ content
Selenium	Not more than 10 mg/kg based on the $SO_2$ content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
<b>E 226 CALCIUM SULPHITE</b>	
<b>Definition</b>	
<i>Chemical name</i>	Calcium sulphite
<b>Einecs</b>	218-235-4
<i>Chemical formula</i>	$CaSO_3 \cdot 2H_2O$
<i>Molecular weight</i>	156,17
<i>Assay</i>	Content not less than 95 % of $CaSO_3 \cdot 2H_2O$ and not less than 39 % of $SO_2$
<i>Description</i>	White crystals or white crystalline powder



**Identification**

A. Positive tests for sulphite and for calcium

**Purity**

Iron	Not more than 50 mg/kg based on the SO <sub>2</sub> content
Selenium	Not more than 10 mg/kg based on the SO <sub>2</sub> content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 227 CALCIUM BISULPHITE****Definition**

<i>Chemical name</i>	Calcium bisulphite Calcium hydrogen sulphite
<i>Einecs</i>	237-423-7
<i>Chemical formula</i>	Ca(HSO <sub>3</sub> ) <sub>2</sub>
<i>Molecular weight</i>	202,22
<i>Assay</i>	6 to 8% (w/v) of sulphur dioxide and 2,5 to 3,5% (w/v) of calcium dioxide corresponding to 10 to 14% (w/v) of calcium bisulphite [Ca(HSO <sub>3</sub> ) <sub>2</sub> ]
<i>Description</i>	Clear greenish-yellow aqueous solution having a distinct odour of sulphur dioxide

**Identification**

A. Positive tests for sulphite and for calcium

**Purity**

Iron	Not more than 50 mg/kg based on the SO <sub>2</sub> content
Selenium	Not more than 10 mg/kg based on the SO <sub>2</sub> content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 228 POTASSIUM BISULPHITE****Definition**

<i>Chemical name</i>	Potassium bisulphite Potassium hydrogen sulphite
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<b>Einecs</b>	231-870-1
<i>Chemical formula</i>	KHSO <sub>3</sub> in aqueous solution
<i>Molecular weight</i>	120,17
<i>Assay</i>	Content not less than 280 g KHSO <sub>3</sub> per litre (or 150 g SO <sub>2</sub> per litre)
<i>Description</i>	Clear colourless aqueous solution
<b>Identification</b>	
A. Positive tests for sulphite and for potassium	
<b>Purity</b>	
Iron	Not more than 50 mg/kg based on the SO <sub>2</sub> content
Selenium	Not more than 10 mg/kg based on the SO <sub>2</sub> content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
<b>E 230 BIPHENYL</b>	
<b>Synonyms</b>	Diphenyl
<b>Definition</b>	
<i>Chemical name</i>	1,1'-biphenyl Phenylbenzene
<b>Einecs</b>	202-163-5
<i>Chemical formula</i>	C <sub>12</sub> H <sub>10</sub>
<i>Molecular weight</i>	154,20
<i>Assay</i>	Content not less than 99,8 %
<i>Description</i>	White or pale yellow to amber crystalline solid having a characteristic odour
<b>Identification</b>	
A. Melting range	68,5°C to 70,5°C
B. Distillation range	It distils completely within a 2,5°C range between 252,5°C and 257,5°C
<b>Purity</b>	
Benzene	Not more than 10 mg/kg
Aromatic amines	Not more than 2 mg/kg (as aniline)
Phenol derivatives	Not more than 5 mg/kg (as phenol)

Readily carbonizable substances	Cold solution of 0,5 g of biphenyl in 5 ml of 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC, 0,3 ml of ferric chloride TSC, 0,1 ml of copper sulphate TSC and 4,4 ml of water
Terphenyl and higher polyphenyl derivatives	Not more than 0,2 %
Polycyclic aromatic hydrocarbons	Absent
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 231 ORTHOPHENYLPHENOL

<b>Synonyms</b>	Orthoxenol
<b>Definition</b>	
<i>Chemical name</i>	(1,1'-Biphenyl)-2-ol 2-Hydroxydiphenyl o-Hydroxydiphenyl
<b>Einecs</b>	201-993-5
<i>Chemical formula</i>	C <sub>12</sub> H <sub>10</sub> O
<i>Molecular weight</i>	170,20
<i>Assay</i>	Content not less than 99 %
<i>Description</i>	White or slightly yellowish crystalline powder
<b>Identification</b>	
A. Melting range	56 °C to 58 °C
B. Positive test for phenolate	An ethanolic solution (1 g in 10 ml) produces a green colour on addition of 10 % ferric chloride solution
<b>Purity</b>	
Sulphated ash	Not more than 0,05 %
Diphenyl ether	Not more than 0,3 %
<i>p</i> -Phenylphenol	Not more than 0,1 %
1-Naphthol	Not more than 0,01 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 232 SODIUM ORTHOPHENYLPHENOL

<b>Synonyms</b>	Sodium orthophenylphenate Sodium salt of o-phenylphenol
<b>Definition</b>	
<i>Chemical name</i>	Sodium orthophenylphenol
<b>Einecs</b>	205-055-6
<i>Chemical formula</i>	$C_{12}H_9ONa \cdot 4H_2O$
<i>Molecular weight</i>	264,26
<i>Assay</i>	Content not less than 97 % of $C_{12}H_9ONa \cdot 4H_2O$
<i>Description</i>	White or slightly yellowish crystalline powder
<b>Identification</b>	
A. Positive tests for phenolate and for sodium	
B. Melting range of orthophenylphenol isolated by acidification and not recrystallized derived from the sample 56 °C to 58 °C after drying in a sulphuric acid desiccator	
C. pH of a 2 % aqueous solution must be between 11,1 and 11,8	
<b>Purity</b>	
Diphenylether	Not more than 0,3 %
<i>p</i> -phenylphenol	Not more than 0,1 %
1-naphthol	Not more than 0,01 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 233 THIABENDAZOLE

<b>Definition</b>	
<i>Chemical name</i>	4-(2-benzimidazolyl)thiazole 2-(4-thiazolyl)-1H-benzimidazole
<b>Einecs</b>	1205-725-8
<i>Chemical formula</i>	$C_{10}H_7N_3S$

<i>Molecular weight</i>	201,26
<i>Assay</i>	Content not less than 98 % on the anhydrous basis
<i>Description</i>	White, or almost white, odourless powder
<b>Identification</b>	
A. Melting range	296 °C to 303 °C
B. Spectrometry	Absorption maxima in 0,1 N HCl (0,0005 % w/v) at 302 nm, 258 nm and 243 nm $E_{1\text{ cm}}^{1\%}$ at 302 nm $\pm 2$ nm: approximately 1 230 $E_{1\text{ cm}}^{1\%}$ at 258 nm $\pm 2$ nm: approximately 200 $E_{1\text{ cm}}^{1\%}$ at 243 nm $\pm 2$ nm: approximately 620 Ratio of absorption 243 nm/302 nm = 0,47 to 0,53 Ratio of absorption 258 nm/302 nm = 0,14 to 0,18
<b>Purity</b>	
Water content	Not more than 0,5 % (Karl Fischer method)
Sulphated ash	Not more than 0,2 %
Selenium	Not more than 3 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
<b>E 234 NISIN</b>	
<b>Definition</b>	Nisin consists of several closely related polypeptides produced by natural strains of <i>Streptococcus lactis</i> , Lancefield group N
<b>Einecs</b>	215-807-5
<b>Chemical formula</b>	$C_{143}H_{230}N_{42}O_{37}S_7$
<b>Molecular weight</b>	3 354,12
<b>Assay</b>	Nisin concentrate contains not less than 900 units per mg in a mixture of non-fat milk solids and a minimum sodium chloride content of 50 %
<b>Description</b>	White powder
<b>Purity</b>	
Loss on drying	Not more than 3 % when dried to constant weight at 102 °C to 103 °C
Arsenic	Not more than 1 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 235 NATAMYCIN

## Synonyms

Pimaricin

## Definition

Natamycin is a fungicide of the polyene macrolide group, and is produced by natural strains of *Streptomyces natalensis* or of *Streptococcus lactis*

## Einecs

231-683-5

## Chemical formula

C<sub>33</sub>H<sub>47</sub>O<sub>13</sub>N

## Molecular weight

665,74

## Assay

Content not less than 95 % on the anhydrous basis

## Description

White to creamy-white crystalline powder

## Identification

## A. Colour reactions

On adding a few crystals of natamycin on a spot plate, to a drop of:

— concentrated hydrochloric acid, a blue colour develops,

— concentrated phosphoric acid, a green colour develops,

which changes into pale red after a few minutes

## B. Spectrometry

A 0,0005 % w/v solution in 1 % methanolic acetic acid solution has absorption maxima at about 290 nm, 303 nm and 318 nm, a shoulder at about 280 nm and exhibits minima at about 250 nm, 295,5 nm and 311 nm

## C. pH

5,5 to 7,5 (1 % w/v solution in previously neutralized mixture of 20 parts dimethylformamide and 80 parts of water)

## D. Specific rotation

$[\alpha]_D^{20} = +250^\circ$  to  $+295^\circ$  (a 1 % w/v solution in glacial acetic acid, at 20°C and calculated with reference to the dried material)

## Purity

## Loss on drying

Not more than 8 % (over P<sub>2</sub>O<sub>5</sub>, in vacuum at 60°C to constant weight)

## Sulphated ash

Not more than 0,5 %

## Arsenic

Not more than 3 mg/kg

## Lead

Not more than 5 mg/kg

## Mercury

Not more than 1 mg/kg

## Heavy metals (as Pb)

Not more than 10 mg/kg

## Microbiological criteria: total viable count

Not more than 100/g

## E 239 HEXAMETHYLENE TETRAMINE

## Synonyms

Hexamine  
Methenamine

## Definition

## Chemical name

1,3,5,7-Tetraazatricyclo [3.3.1.1<sup>3,7</sup>]-decane, hexamethylenetetramine

## Einecs

202-905-8

<i>Chemical formula</i>	$C_6H_{12}N_4$
<i>Molecular weight</i>	140,19
<i>Assay</i>	Content not less than 99 % on the anhydrous basis
<i>Description</i>	Colourless or white crystalline powder
<b>Identification</b>	
A. Positive tests for formaldehyde and for ammonia	
B. Sublimation point approximately 260 °C	
<b>Purity</b>	
Loss on drying	Not more than 0,5 % after drying at 105 °C in vacuum over $P_2O_5$ for two hours
Sulphated ash	Not more than 0,05 %
Sulphates	Not more than 0,005 % expressed as $SO_4$
Chlorides	Not more than 0,005 % expressed as Cl
Ammonium salts	Not detectable
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
<b>E 242 DIMETHYL DICARBONATE</b>	
<b>Synonyms</b>	DMDC Dimethyl pyrocarbonate
<b>Definition</b>	
<b>Einecs</b>	224-859-8
<i>Chemical name</i>	Dimethyl dicarbonate Pyrocarbonic acid dimethyl ester
<i>Chemical formula</i>	$C_4H_6O_5$
<i>Molecular weight</i>	134,09
<i>Assay</i>	Content not less than 99,8 %
<i>Description</i>	Colourless liquid, decomposes in aqueous solution. It is corrosive to skin and eyes and toxic by inhalation and ingestion

**Identification**

A. Decomposition	After dilution positive tests for CO <sub>2</sub> and methanol
B. Melting point	17°C
Boiling point	172°C with decomposition
C. Density 20°C	Approximately 1,25 g/cm <sup>3</sup>
D. Infrared spectrum	Maxima at 1 156 and 1 832 cm <sup>-1</sup>

**Purity**

Dimethyl carbonate	Not more than 0,2 %
Chlorine, total	Not more than 3 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 249 POTASSIUM NITRITE****Definition**

<i>Chemical name</i>	Potassium nitrite
<b>Einecs</b>	231-832-4
<i>Chemical formula</i>	KNO <sub>2</sub>
<i>Molecular weight</i>	85,11
<i>Assay</i>	Content not less than 95 % on the anhydrous basis <sup>(1)</sup>
<i>Description</i>	White or slightly yellow, deliquescent granules

**Identification**

- A. Positive tests for nitrite and for potassium
- B. pH of a 5 % solution: not less than 6,0 and not more than 9,0

**Purity**

Loss on drying	Not more than 3 % after drying for four hours over silica gel
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

<sup>(1)</sup> When labelled 'for food use', nitrite may only be sold in a mixture with salt or a salt substitute.



## E 250 SODIUM NITRITE

## Definition

<i>Chemical name</i>	Sodium nitrite
<b>Einecs</b>	231-555-9
<i>Chemical formula</i>	NaNO <sub>2</sub>
<i>Molecular weight</i>	69,00
<i>Assay</i>	Content not less than 97% on the anhydrous basis <sup>(1)</sup>
<i>Description</i>	White crystalline powder or yellowish lumps

## Identification

A. Positive tests for nitrite and for sodium

## Purity

Loss on drying	Not more than 0,25% after drying over silica gel for four hours
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 251 SODIUM NITRATE

## Synonyms

Chile saltpetre  
Cubic or soda nitre

## Definition

<i>Chemical name</i>	Sodium nitrate
<b>Einecs</b>	231-554-3
<i>Chemical formula</i>	NaNO <sub>3</sub>
<i>Molecular weight</i>	85,00
<i>Assay</i>	Content not less than 99% after drying at 105°C for four hours
<i>Description</i>	White crystalline, slightly hygroscopic powder

## Identification

A. Positive tests for nitrate and for sodium	
B. pH of a 5% solution	Not less than 5,5 and more than 8,3
C. Melting point: ±308°C	

<sup>(1)</sup> When labelled 'for food use', nitrite may only be sold in a mixture with salt or a salt substitute.

**Purity**

Loss on drying	Not more than 2 % after drying at 105 °C for four hours
Nitrites	Not more than 30 mg/kg expressed as NaNO <sub>2</sub>
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 252 POTASSIUM NITRATE****Synonyms**

Chile saltpetre  
Cubic or soda nitre

**Definition***Chemical name*

Potassium nitrate

*Einecs*

231-818-8

*Chemical formula*KNO<sub>3</sub>*Molecular weight*

101,11

*Assay*

Content not less than 99 % on the anhydrous basis

*Description*

White crystalline powder or transparent prisms having a cooling, saline, pungent taste

**Identification**

A. Positive tests for nitrate and for potassium

B. pH of a 5 % solution

Not less than 4,5 and not more than 8,5

**Purity**

Loss on drying	Not more than 1 % after drying at 105 °C for four hours
Nitrites	Not more than 20 mg/kg expressed as KNO <sub>2</sub>
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 260 ACETIC ACID****Definition***Chemical name*Acetic acid  
Ethanoic acid

<b>Einecs</b>	200-580-7
<i>Chemical formula</i>	$C_2H_4O_2$
<i>Molecular weight</i>	60,05
<i>Assay</i>	Content not less than 99,8 %
<i>Description</i>	Clear, colourless liquid having a pungent, characteristic odour
<b>Identification</b>	
A. Boiling point	118°C at 760 mm pressure (of mercury)
B. Specific gravity	About 1,049
C. A one in three solution gives positive tests for acetate	
D. Solidification point	Not lower than 14,5°C
<b>Purity</b>	
Non-volatile residue	Not more than 100 mg/kg
Formic acid, formates and other oxidizable substances	Not more than 1 000 mg/kg expressed as formic acid
Readily oxidizable substances	Dilute 2 ml of the sample in a glass-stoppered container with 10 ml of water and add 0,1 ml of 0,1 N potassium permanganate. The pink colour does not change to brown within 30 minutes
Arsenic	Not more than 1 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 261 POTASSIUM ACETATE**

<b>Definition</b>	
<i>Chemical name</i>	Potassium acetate
<b>Einecs</b>	204-822-2
<i>Chemical formula</i>	$C_2H_3O_2K$
<i>Molecular weight</i>	98,14
<i>Assay</i>	Content not less than 99 % on the anhydrous basis
<i>Description</i>	Colourless, deliquescent crystals or a white crystalline powder, odourless or with a faint acetic odour
<b>Identification</b>	
A. pH of a 5 % aqueous solution	Not less than 7,5 and not more than 9,0
B. Positive tests for acetate and for potassium	

**Purity**

Loss on drying	Not more than 8 % after drying at 150°C for two hours
Formic acid, formates and other oxidizable substances	Not more than 1 000 mg/kg expressed as formic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 262 (i) SODIUM ACETATE****Definition**

<i>Chemical name</i>	Sodium acetate
<b>Einecs</b>	204-823-8
<i>Chemical formula</i>	$C_2H_3NaO_2 \cdot nH_2O$ (n = 0 or 3)
<i>Molecular weight</i>	Anhydrous: 82,03 Trihydrate: 136,08
<i>Assay</i>	Content (for both of anhydrous and trihydrate form) not less than 98,5 % on the anhydrous basis
<i>Description</i>	Anhydrous: White, odourless, granular, hygroscopic powder Trihydrate: Colourless, transparent crystals or a granular crystalline powder, odourless or with a faint, acetic odour. Effloresces in warm, dry air

**Identification**

A. pH of a 1 % aqueous solution	Not less than 8,0 and not more than 9,5
B. Positive tests for acetate and for sodium	

**Purity**

Loss on drying	Anhydrous: Not more than 2 % (120°C, 4 hours) Trihydrate: Between 36 and 42 % (120°C, 4 hours)
Formic acid, formates and other oxidizable substances	Not more than 1 000 mg/kg expressed as formic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 262 (ii) SODIUM DIACETATE

<b>Definition</b>	Sodium diacetate is a molecular compound of sodium acetate and acetic acid
<i>Chemical name</i>	Sodium hydrogen diacetate
<b>Einecs</b>	204-814-9
<i>Chemical formula</i>	$C_4H_7NaO_4 \cdot nH_2O$ (n = 0 or 3)
<i>Molecular weight</i>	142,09 (anhydrous)
<i>Assay</i>	Content 39 to 41 % of free acetic acid and 58 to 60 % of sodium acetate
<i>Description</i>	White, hygroscopic crystalline solid with an acetic odour
<b>Identification</b>	
A. pH of a 10 % aqueous solution	Not less than 4,5 and not more than 5,0
B. Positive tests for acetate and for sodium	
<b>Purity</b>	
Water content	Not more than 2 % (Karl Fischer method)
Formic acid, formates and other oxidizable substances	Not more than 1 000 mg/kg expressed as formic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 263 CALCIUM ACETATE

<b>Definition</b>	
<i>Chemical name</i>	Calcium acetate
<b>Einecs</b>	200-540-9
<i>Chemical formula</i>	Anhydrous: $C_4H_6O_4Ca$ Monohydrate: $C_4H_6O_4Ca \cdot H_2O$
<i>Molecular weight</i>	Anhydrous: 158,17 Monohydrate: 176,18
<i>Assay</i>	Content not less than 98 % on the anhydrous basis
<i>Description</i>	Anhydrous calcium acetate is a white, hygroscopic, bulky, crystalline solid with a slightly bitter taste. A slight odour of acetic acid may be present. The monohydrate may be needles, granules or powder
<b>Identification</b>	
A. pH of a 10 % aqueous solution	Not less than 6,0 and not more than 9,0
B. Positive tests for acetate and for calcium	

**Purity**

Loss on drying	Not more than 11 % after drying (155 °C to constant weight, for the monohydrate)
Water insoluble matter	Not more than 0,3 %
Formic acid, formates and other oxidizable substances	Not more than 1 000 mg/kg expressed as formic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 270 LACTIC ACID****Definition**

<i>Chemical name</i>	Lactic acid 2-Hydroxypropionic acid 1-Hydroxyethane-1-carboxylic acid
<b>Einecs</b>	200-018-0
<i>Chemical formula</i>	$C_3H_6O_3$
<i>Molecular weight</i>	90,08
<i>Assay</i>	Content not less than 76 % and not more than 84 %
<i>Description</i>	Colourless or yellowish, nearly odourless, syrupy liquid with an acid taste, consisting of a mixture of lactic acid ( $C_3H_6O_3$ ) and lactic acid lactate ( $C_6H_{10}O_5$ ). It is obtained by the lactic fermentation of sugars or is prepared synthetically
<i>Note:</i>	
Lactic acid is hygroscopic and when concentrated by boiling, it condenses to form lactic acid lactate, which on dilution and heating hydrolyzes to lactic acid	

**Identification**

- A. Positive test for lactate

**Purity**

Sulphated ash	Not more than 0,1 %
Chloride	Not more than 0,2 %
Sulphate	Not more than 0,25 %
Iron	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
<i>Note:</i>	
This specification refers to a 80 % aqueous solution; for weaker aqueous solutions, calculate values corresponding to their lactic acid content	
<b>E 280 PROPIONIC ACID</b>	
<b>Definition</b>	
<i>Chemical name</i>	Propionic acid Propanoic acid
<b>Einecs</b>	201-176-3
<i>Chemical formula</i>	C <sub>3</sub> H <sub>6</sub> O <sub>2</sub>
<i>Molecular weight</i>	74,08
<i>Assay</i>	Content not less than 99,5 %
<i>Description</i>	Colourless or slightly yellowish, oily liquid with a slightly pungent odour
<b>Identification</b>	
A. Melting point	-22 °C
B. Distillation range	138,5 °C to 142,5 °C
<b>Purity</b>	
Non-volatile residue	Not more than 0,01 % when dried at 140 °C to constant weight
Aldehydes	Not more than 0,1 % expressed as formaldehyde
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 281 SODIUM PROPIONATE**

<b>Definition</b>	
<i>Chemical name</i>	Sodium propionate Sodium propanoate
<b>Einecs</b>	205-290-4
<i>Chemical formula</i>	C <sub>3</sub> H <sub>5</sub> O <sub>2</sub> Na
<i>Molecular weight</i>	96,06
<i>Assay</i>	Content not less than 99 % after drying for two hours at 105 °C
<i>Description</i>	White crystalline hygroscopic powder, or a fine white powder

**Identification**

- A. Positive tests for propionate and for sodium
- B. pH of a 10% aqueous solution
- Not less than 7,5 and not more than 10,5

**Purity**

- Loss on drying
- Water insolubles
- Iron
- Arsenic
- Lead
- Mercury
- Heavy metals (as Pb)
- Not more than 4% determined by drying for two hours at 105°C
- Not more than 0,1%
- Not more than 50 mg/kg
- Not more than 3 mg/kg
- Not more than 5 mg/kg
- Not more than 1 mg/kg
- Not more than 10 mg/kg

**E 282 CALCIUM PROPIONATE****Definition**

- Chemical name*
- Einecs*
- Chemical formula*
- Molecular weight*
- Assay*
- Description*
- Calcium propionate
- 223-795-8
- $C_6H_{10}O_4Ca$
- 186,22
- Content not less than 99%, after drying for two hours at 105°C
- White crystalline powder

**Identification**

- A. Positive tests for propionate and for calcium
- B. pH of a 10% aqueous solution
- Between 6,0 and 9,0

**Purity**

- Loss on drying
- Water insolubles
- Iron
- Fluoride
- Arsenic
- Lead
- Mercury
- Heavy metals (as Pb)
- Not more than 4%, determined by drying for two hours at 105°C
- Not more than 0,3%
- Not more than 50 mg/kg
- Not more than 10 mg/kg
- Not more than 3 mg/kg
- Not more than 5 mg/kg
- Not more than 1 mg/kg
- Not more than 10 mg/kg



## E 283 POTASSIUM PROPIONATE

## Definition

<i>Chemical name</i>	Potassium propionate Potassium propanoate
<i>Einecs</i>	206-323-5
<i>Chemical formula</i>	$C_3H_5KO_2$
<i>Molecular weight</i>	112,17
<i>Assay</i>	Content not less than 99% after drying for two hours at 105°C
<i>Description</i>	White crystalline powder

## Identification

- A. Positive tests for propionate and for potassium

## Purity

Loss on drying	Not more than 4%, determined by drying for two hours at 105°C
Water-insoluble substances	Not more than 0,3%
Iron	Not more than 30 mg/kg
Fluoride	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 284 BORIC ACID

## Synonyms

Boracic acid  
Orthoboric acid  
Borofax

## Definition

<i>Einecs</i>	233-139-2
<i>Chemical formula</i>	$H_3BO_3$
<i>Molecular weight</i>	61,84
<i>Assay</i>	Content not less than 99,5%
<i>Description</i>	Colourless, odourless, transparent crystals or white granules or powder; slightly unctuous to the touch; occurs in nature as the mineral sassolite

## Identification

- A. Melting point  
At approximately 171°C
- B. Burns with a nice green flame
- C. pH of a 3,3% aqueous solution  
Between 3,8 and 4,8

**Purity**

Peroxides	No colour develops with added KI-solution
Arsenic	Not more than 1 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 285 SODIUM TETRABORATE (BORAX)****Synonyms**

Sodium borate

**Definition***Chemical name*Sodium tetraborate  
Sodium baborate  
Sodium pyroborate  
Anhydrous tetraborate**Einecs**

215-540-4

*Chemical formula* $\text{Na}_2\text{B}_4\text{O}_7$   
 $\text{Na}_2\text{B}_4\text{O}_7 \cdot 10\text{H}_2\text{O}$ *Molecular weight*

201,27

*Description*

Powder or glass-like plates becoming opaque on exposure to air; slowly soluble in water

**Identification**

## A. Melting range

Between 171°C and 175°C with decomposition

**Purity**

Peroxides	No colour develops with added KI-solution
Arsenic	Not more than 1 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 290 CARBON DIOXIDE****Synonyms**Carbonic acid gas  
Dry ice (solid form)  
Carbonic anhydride**Definition***Chemical name*

Carbon dioxide

**Einecs**

204-696-9

<i>Chemical formula</i>	CO <sub>2</sub>
<i>Molecular weight</i>	44,01
<i>Assay</i>	Content not less than 99% v/v on the gaseous basis
<i>Description</i>	A colourless gas under normal environmental conditions with a slight pungent odour. Commercial carbon dioxide is shipped and handled as a liquid in pressurized cylinders or bulk storage systems, or in compressed solid blocks of 'dry ice'. Solid (dry ice) forms usually contain added substances, such as propylene glycol or mineral oil, as binders
<b>Identification</b>	
A. Precipitation (Precipitate formation)	When a stream of the sample is passed through a solution of barium hydroxide, a white precipitate is produced which dissolves with effervescence in dilute acetic acid
<b>Purity</b>	
Acidity	915 ml of gas bubbled through 50 ml of freshly boiled water must not render the latter more acid to methylorange than is 50 ml freshly boiled water to which has been added 1 ml of hydrochloric acid (0,01 N)
Reducing substances, hydrogen phosphide and sulphide	915 ml of gas bubbled through 25 ml of ammoniacal silver nitrate reagent to which has been added 3 ml of ammonia must not cause clouding or blackening of this solution
Carbon monoxide	Not more than 10 µl/l
Oil content	Not more than 0,1 mg/l

**E 300 ASCORBIC ACID****Definition**

<i>Chemical name</i>	L-ascorbic acid Ascorbic acid 2,3-Didehydro-L-threo-hexono-1,4-lactone 3-Keto-L-gulofuranolactone
<b>Einecs</b>	200-066-2
<i>Chemical formula</i>	C <sub>6</sub> H <sub>8</sub> O <sub>6</sub>
<i>Molecular weight</i>	176,13
<i>Assay</i>	Ascorbic acid, after drying in a vacuum desiccator over sulphuric acid for 24 hours, contains not less than 99% of C <sub>6</sub> H <sub>8</sub> O <sub>6</sub>
<i>Description</i>	White to pale yellow, odourless crystalline solid
<b>Identification</b>	
A. Melting range	Between 189°C and 193°C with decomposition
B. Positive tests for ascorbic acid	
<b>Purity</b>	
Loss on drying	Not more than 0,4% after drying in a vacuum desiccator over sulphuric acid for 24 hours
Sulphated ash	Not more than 0,1%

Specific rotation	$[\alpha]_D^{20}$ between +20,5° and +21,5° (10 % w/v aqueous solution)
pH of a 2 % aqueous solution	Between 2,4 and 2,8
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 301 SODIUM ASCORBATE****Definition***Chemical name*

Sodium ascorbate  
Sodium L-ascorbate  
2,3-Didehydro-L-threo-hexono-1,4-lactone sodium enolate  
3-Keto-L-gulofurano-lactone sodium enolate

**Einecs**

205-126-1

*Chemical formula* $C_6H_7O_6Na$ *Molecular weight*

198,11

*Assay*

Sodium ascorbate, after drying in a vacuum desiccator over sulphuric acid for 24 hours, contains not less than 99 % of  $C_6H_7O_6Na$

*Description*

White or almost white, odourless crystalline solid which darkens on exposure to light

**Identification**

## A. Positive tests for ascorbate and for sodium

**Purity**

## Loss on drying

Not more than 0,25 % after drying in a vacuum desiccator over sulphuric acid for 24 hours

## Specific rotation

 $[\alpha]_D^{20}$  between +103° and +106° (10 % w/v aqueous solution)

## pH of 10 % aqueous solution

Between 6,5 and 8,0

## Arsenic

Not more than 3 mg/kg

## Lead

Not more than 5 mg/kg

## Mercury

Not more than 1 mg/kg

## Heavy metals (as Pb)

Not more than 10 mg/kg

**E 302 CALCIUM ASCORBATE****Definition***Chemical name*

Calcium ascorbate dihydrate  
Calcium salt of 2,3-didehydro-L-threo-hexono-1,4-lactone dihydrate

<b>Einecs</b>	227-261-5
<i>Chemical formula</i>	$C_{12}H_{14}O_{12}Ca \cdot 2H_2O$
<i>Molecular weight</i>	426,35
<i>Assay</i>	Content not less than 98 % on a volatile matter-free basis
<i>Description</i>	White to slightly pale greyish-yellow odourless crystalline powder
<b>Identification</b>	
A. Positive tests for ascorbate and for calcium	
<b>Purity</b>	
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Specific rotation	$[\alpha]_D^{20}$ between $+95^\circ$ and $+97^\circ$ (5 % w/v aqueous solution)
pH of 10 % aqueous solution	Between 6,0 and 7,5
Volatile matter	Not more than 0,3 % determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 304 (i) ASCORBYL PALMITATE**

<b>Definition</b>	
<i>Chemical name</i>	Ascorbyl palmitate L-ascorbyl palmitate 2,3-didehydro-L-threo-hexono-1,4-lactone-6-palmitate 6-palmitoyl-3-keto-L-gulofuranolactone
<b>Einecs</b>	205-305-4
<i>Chemical formula</i>	$C_{22}H_{38}O_7$
<i>Molecular weight</i>	414,55
<i>Assay</i>	Content not less than 98 % on the dried basis
<i>Description</i>	White or yellowish-white solid with a citrus-like odour
<b>Identification</b>	
A. Melting range	Between $107^\circ C$ and $117^\circ C$
<b>Purity</b>	
Loss on drying	Not more than 2,0 % after drying in a vacuum oven at $56^\circ C$ and $60^\circ C$ for one hour
Sulphated ash	Not more than 0,1 %

Specific rotation	$[\alpha]_D^{20}$ between +21° and +24° (5% w/v in methanol solution)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 304 (ii) ASCORBYL STEARATE****Definition**

<i>Chemical name</i>	Ascorbyl stearate L-ascorbyl stearate 2,3-didehydro-L-threo-hexono-1,4-lactone-6-stearate 6-stearoyl-3-keto-L-gulofuranolactone
<b>Einecs</b>	246-944-9
<i>Chemical formula</i>	$C_{24}H_{42}O_7$
<i>Molecular weight</i>	442,6
<i>Assay</i>	Content not less than 98 %
<i>Description</i>	White or yellowish, white solid with a citrus-like odour

**Identification**

A. Melting point	About 116 °C
------------------	--------------

**Purity**

Loss on drying	Not more than 2,0 % after drying in a vacuum oven at 56 °C to 60 °C for one hour
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 306 TOCOPHEROL-RICH EXTRACT****Definition**

	Product obtained by the vacuum steam distillation of edible vegetable oil products, comprising concentrated tocopherols and tocotrienols Contains tocopherols such as d- $\alpha$ -, d- $\beta$ -, d- $\gamma$ - and d- $\zeta$ -tocopherols
<i>Molecular weight</i>	430,71 (d- $\alpha$ -tocopherol)
<i>Assay</i>	Content not less than 34 % of total tocopherols
<i>Description</i>	Brownish red to red, clear, viscous oil having a mild, characteristic odour and taste. May show a slight separation of wax-like constituents in microcrystalline form

**Identification**

A. By suitable gas liquid chromatographic method

B. Solubility tests

Insoluble in water. Soluble in ethanol. Miscible in ether

**Purity**

Sulphated ash

Not more than 0,1 %

Specific rotation

$[\alpha]_D^{20}$  not less than +20°

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 mg/kg

**E 307 ALPHA-TOCOPHEROL****Synonyms**

dl- $\alpha$ -Tocopherol

**Definition**

*Chemical name*

dl-5,7,8-Trimethyltolcol  
dl-2,5,7,8-tetramethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol

*Einecs*

200-412-2

*Chemical formula*

$C_{29}H_{50}O_2$

*Molecular weight*

430,71

*Assay*

Content not less than 96 %

*Description*

Slightly yellow to amber, nearly odourless, clear, viscous oil which oxidizes and darkens on exposure to air or light

**Identification**

A. Solubility tests

Insoluble in water, freely soluble in ethanol, miscible in ether

B. Spectrophotometry

In absolute ethanol the maximum absorption is about 292 nm

**Purity**

Refractive index

$n_D^{20}$  1,503 — 1,507

Specific absorption  $E_{1\text{ cm}}^{1\%}$  in ethanol

$E_{1\text{ cm}}^{1\%}$  (292 nm) 72—76  
(0,01 g in 200 ml of absolute ethanol)

Sulphated ash

Not more than 0,1 %

Specific rotation

$[\alpha]_D^{20}$   $0^\circ \pm 0,05^\circ$  (1 in 10 solution in chloroform)

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 mg/kg

## E 308 GAMMA-TOCOPHEROL

<b>Synonyms</b>	dl- $\gamma$ -Tocopherol
<b>Definition</b>	
<i>Chemical name</i>	2,7,8-trimethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol
<i>Einecs</i>	231-523-4
<i>Chemical formula</i>	$C_{28}H_{48}O_2$
<i>Molecular weight</i>	416,69
<i>Assay</i>	Content not less than 97 %
<i>Description</i>	Clear, viscous, pale yellow oil which oxidizes and darkens on exposure to air or light
<b>Identification</b>	
A. Spectrometry	Maximum absorptions in absolute ethanol at about 298 nm and 257 nm
<b>Purity</b>	
Specific absorption $E_{1\text{cm}}^{1\%}$ in ethanol	$E_{1\text{cm}}^{1\%}$ (298 nm) between 91 and 97 $E_{1\text{cm}}^{1\%}$ (257 nm) between 5,0 and 8,0
Refractive index	$n_D^{20}$ 1,503—1,507
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 309 DELTA-TOCOPHEROL

<b>Definition</b>	
<i>Chemical name</i>	2,8-dimethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol
<i>Einecs</i>	204-299-0
<i>Chemical formula</i>	$C_{27}H_{46}O_2$
<i>Molecular weight</i>	402,7
<i>Assay</i>	Content not less than 97 %
<i>Description</i>	Clear, viscous, pale yellowish or orange oil which oxidizes and darkens on exposure to air or light
<b>Identification</b>	
A. Spectrometry	Maximum absorptions in absolute ethanol at about 298 nm and 257 nm



**Purity**

Specific absorption $E_{1\text{ cm}}^{1\%}$ in ethanol	$E_{1\text{ cm}}^{1\%}$ (298 nm) between 89 and 95 $E_{1\text{ cm}}^{1\%}$ (257 nm) between 3,0 and 6,0
Refractive index	$n_D^{20}$ 1,500—1,504
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 310 PROPYL GALLATE****Definition**

<i>Chemical name</i>	Propyl gallate Propyl ester of gallic acid n-propyl ester of 3,4,5-trihydroxybenzoic acid
<b>Einecs</b>	204-498-2
<i>Chemical formula</i>	$C_{10}H_{12}O_5$
<i>Molecular weight</i>	212,20
<i>Assay</i>	Content not less than 98 % on the anhydrous basis
<i>Description</i>	White to creamy-white, crystalline, odourless solid

**Identification**

A. Solubility tests	Slightly soluble in water, freely soluble in ethanol, ether and propane-1,2-diol
B. Melting range	Between 146 °C and 150 °C after drying at 110 °C for four hours

**Purity**

Loss on drying	Not more than 1,0 % (110 °C, four hours)
Sulphated ash	Not more than 0,1 %
Free acid	Not more than 0,5 % (as gallic acid)
Chlorinated organic compound	Not more than 100 mg/kg (as Cl)
Specific absorption $E_{1\text{ cm}}^{1\%}$ in ethanol	$E_{1\text{ cm}}^{1\%}$ (275 nm) not less than 485 and not more than 520
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 311 OCTYL GALLATE

## Definition

<i>Chemical name</i>	Octyl gallate Octyl ester of gallic acid n-octyl ester of 3,4,5-trihydroxybenzoic acid
Einecs	213-853-0
<i>Chemical formula</i>	C <sub>15</sub> H <sub>22</sub> O <sub>5</sub>
<i>Molecular weight</i>	282,34
<i>Assay</i>	Content not less than 98 % after drying at 90 °C for six hours
<i>Description</i>	White to creamy-white odourless solid

## Identification

A. Solubility tests	Insoluble in water, freely soluble in ethanol, ether and propane-1,2-diol
B. Melting range	Between 99 °C and 102 °C after drying at 90 °C for six hours

## Purity

Loss on drying	Not more than 0,5 % (90 °C, six hours)
Sulphated ash	Not more than 0,05 %
Free acid	Not more than 0,5 % (as gallic acid)
Chlorinated organic compound	Not more than 100 mg/kg (as Cl)
Specific absorption E <sub>1cm</sub> <sup>1%</sup> in ethanol	E <sub>1cm</sub> <sup>1%</sup> (275 nm) not less than 375 and not more than 390
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 312 DODECYL GALLATE

## Synonyms

Lauryl gallate

## Definition

<i>Chemical name</i>	Dodecyl gallate n-dodecyl (or lauryl) ester of 3,4,5-trihydroxybenzoic acid Dodecyl ester of gallic acid
Einecs	214-620-6
<i>Chemical formula</i>	C <sub>19</sub> H <sub>30</sub> O <sub>5</sub>
<i>Molecular weight</i>	338,45
<i>Assay</i>	Content not less than 98 % after drying at 90 °C for six hours
<i>Description</i>	White or creamy-white odourless solid

**Identification**

A. Solubility tests

Insoluble in water, freely soluble in ethanol and ether

B. Melting range

Between 95°C and 98°C after drying at 90°C for six hours

**Purity**

Loss on drying

Not more than 0,5% (90°C, six hours)

Sulphated ash

Not more than 0,05%

Free acid

Not more than 0,5% (as gallic acid)

Chlorinated organic compound

Not more than 100 mg/kg (as Cl)

Specific absorption  $E_{1\text{cm}}^{1\%}$  in ethanol $E_{1\text{cm}}^{1\%}$  (275 nm) not less than 300 and not more than 325

Arsenic

Not more than 3 mg/kg

Lead

Not more than 10 mg/kg

Mercury

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 30 mg/kg

**E 315 ERYTHORBIC ACID****Synonyms**Isoascorbic acid  
D-araboascorbic acid**Definition***Chemical name*D-Erythro-hex-2-enoic acid  $\gamma$ -lactone  
Isoascorbic acid  
D-isoascorbic acid**Einecs**

201-928-0

*Chemical formula* $C_6H_8O_6$ *Molecular weight*

176,13

*Assay*

Content not less than 98% on the anhydrous basis

*Description*

White to slightly yellow crystalline solid which darkens gradually on exposure to light

**Identification**

A. Melting range

About 164°C to 172°C with decomposition

B. Positive test for ascorbic acid/colour reaction

**Purity**

Loss on drying

Not more than 0,4% after drying under reduced pressure on silica gel for 3 hours

Sulphated ash

Not more than 0,3%

Specific rotation	$[\alpha]_D^{25}$ 10 % (w/v) aqueous solution between $-16,5^\circ$ to $-18,0^\circ$
Oxalate	To a solution of 1 g in 10 ml of water add 2 drops of glacial acetic acid and 5 ml of 10 % calcium acetate solution. The solution should remain clear
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 316 SODIUM ERYTHORBATE

<b>Synonyms</b>	Sodium isoascorbate
<b>Definition</b>	
<i>Chemical name</i>	Sodium isoascorbate Sodium D-isoascorbic acid Sodium salt of 2,3-didehydro-D-erythro-hexono-1,4-lactone 3-keto-D-gulofurano-lactone sodium enolate monohydrate
<b>Einécs</b>	228-973-9
<i>Chemical formula</i>	$C_6H_7O_6Na \cdot H_2O$
<i>Molecular weight</i>	216,13
<i>Assay</i>	Content not less than 98 % after drying in a vacuum desiccator over sulphuric acid for 24 hours expressed on the monohydrate basis
<i>Description</i>	White crystalline solid
<b>Identification</b>	
A. Solubility tests	Freely soluble in water, very slightly soluble in ethanol
B. Positive test for ascorbic acid/colour reaction	
C. Positive test for sodium	
<b>Purity</b>	
Loss on drying	Not more than 0,25 % after drying in a vacuum desiccator over sulphuric acid for 24 hours
Specific rotation	$[\alpha]_D^{25}$ 10 % (w/v) aqueous solution between $+95^\circ$ and $+98^\circ$
pH of a 10 % aqueous solution	5,5 to 8,0
Oxalate	To a solution of 1 g in 10 ml of water add 2 drops of glacial acetic acid and 5 ml of 10 % calcium acetate solution. The solution should remain clear
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 320 BUTYLATED HYDROXYANISOLE (BHA)

<b>Synonyms</b>	BHA
<b>Definition</b>	
<i>Chemical name</i>	3-Tertiary-butyl-4-hydroxyanisole A mixture of 2-tertiarybutyl-4-hydroxyanisole and 3-tertiarybutyl-4-hydroxyanisole
<b>Einecs</b>	246-563-8
<i>Chemical formula</i>	C <sub>11</sub> H <sub>16</sub> O <sub>2</sub>
<i>Molecular weight</i>	180,25
<i>Assay</i>	Content not less than 98,5 % of C <sub>11</sub> H <sub>16</sub> O <sub>2</sub> and not less than 85 % of 3-tertiary-butyl-4-hydroxyanisole isomer
<i>Description</i>	White or slightly yellow crystals or waxy solid with a slight aromatic smell
<b>Identification</b>	
A. Solubility tests	Insoluble in water
B. Melting range	Between 48 °C and 55 °C
<b>Purity</b>	
Sulphated ash	Not more than 0,05 % after calcination at 800 ± 25 °C
Phenolic impurities	Not more than 0,5 %
Specific absorption E <sub>1 cm</sub> <sup>1%</sup> in ethanol	E <sub>1 cm</sub> <sup>1%</sup> (290 nm) not less than 190 and not more than 210 E <sub>1 cm</sub> <sup>1%</sup> (228 nm) not less than 326 and not more than 345
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 321 BUTYLATED HYDROXYTOLUENE (BHT)

<b>Synonyms</b>	BHT
<b>Definition</b>	
<i>Chemical name</i>	2,6-Ditertiary-butyl- <i>p</i> -cresol 4-Methyl-2,6-ditertiarybutylphenol
<b>Einecs</b>	204-881-4
<i>Chemical formula</i>	C <sub>15</sub> H <sub>24</sub> O
<i>Molecular weight</i>	220,36
<i>Assay</i>	Content not less than 99 %
<i>Description</i>	White, crystalline or flaked solid, odourless or having a characteristic faint aromatic odour

**Identification**

- |                       |  |
|-----------------------|--|
| A. Solubility tests   | Insoluble in water and propane- 1,2-diol .<br>Freely soluble in ethanol  |
| B. Melting point      | At 70°C  |
| C. Absorbance maximum | The absorption in the range 230 to 320 nm of a 2 cm layer of a 1 in 100 000 solution in dehydrated ethanol exhibits a maximum only at 278 nm |

**Purity**

- |   |   |
|---|---|
| Sulphated ash   | Not more than 0,005 %   |
| Phenolic impurities                                   | Not more than 0,5 %   |
| Specific absorption $E_{1\text{cm}}^{1\%}$ in ethanol | $E_{1\text{cm}}^{1\%}$ (278 nm) not less than 81 and not more than 88 |
| Arsenic   | Not more than 3 mg/kg   |
| Lead  | Not more than 5 mg/kg   |
| Mercury   | Not more than 1 mg/kg   |
| Heavy metals (as Pb)                                  | Not more than 10 mg/kg  |

**E 322 LECITHINS****Synonyms**

Phosphatides  
Phospholipids

**Definition**

Lecithins are mixtures or fractions of phosphatides obtained by physical procedures from animal or vegetable foodstuffs; they also include hydrolysed products obtained through the use of harmless and appropriate enzymes. The final product must not show any signs of residual enzyme activity

The lecithins may be slightly bleached in aqueous medium by means of hydrogen peroxide. This oxidation must not chemically modify the lecithin phosphatides

**Einecs**

232-307-2

**Assay**

- Lecithins: not less than 60,0 % of substances insoluble in acetone
- Hydrolysed lecithins: not less than 56,0 % of substances insoluble in acetone

**Description**

- Lecithins: brown liquid or viscous semi-liquid or powder
- Hydrolysed lecithins: light brown to brown viscous liquid or paste

**Identification**

- |   |  |
|---|--|
| A. Positive tests for choline, for phosphorus and fatty acids |  |
| B. Test for hydrolysed lecithin                               |  |

To a 800 ml beaker add 500 ml of water (30°C—35°C). Then slowly add 50 ml of the sample with constant stirring. Hydrolysed lecithin will form a homogeneous emulsion. Non-hydrolysed lecithin will form a distinct mass of about 50 g

**Purity**

- |                          |   |
|--------------------------|---|
| Loss on drying           | Not more than 2,0 % determined by drying at 105°C for one hour  |
| Toluene-insoluble matter | Not more than 0,3 %   |
| Acid value               | — Lecithins: not more than 35 mg of potassium hydroxide per gram<br>— Hydrolysed lecithins: not more than 45 mg of potassium hydroxide per gram |

Peroxide value	Equal to or less than 10
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 325 SODIUM LACTATE

## Definition

<i>Chemical name</i>	Sodium lactate Sodium 2-hydroxypropanoate
<i>Einecs</i>	200-772-0
<i>Chemical formula</i>	C <sub>3</sub> H <sub>5</sub> NaO <sub>3</sub>
<i>Molecular weight</i>	112,06 (anhydrous)
<i>Assay</i>	Content not less than 57% and not more than 66%
<i>Description</i>	Colourless, transparent, liquid Odourless, or with a slight, characteristic odour

## Identification

- A. Positive test for lactate
- B. Positive test for potassium

## Purity

Acidity	Not more than 0,5% after drying expressed as lactic acid
pH of a 20% aqueous solution	6,5 to 7,5
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Reducing substances	No reduction of Fehling's solution

*Note:*

This specification refers to a 60% aqueous solution

## E 326 POTASSIUM LACTATE

## Definition

<i>Chemical name</i>	Potassium lactate Potassium 2-hydroxypropanoate
<i>Einecs</i>	213-631-3

<i>Chemical formula</i>	C <sub>3</sub> H <sub>5</sub> O <sub>3</sub> K
<i>Molecular weight</i>	128,17 (anhydrous)
<i>Assay</i>	Content not less than 57% and not more than 66%
<i>Description</i>	Slightly viscous, almost odourless clear liquid. Odourless, or with a slight, characteristic odour
<b>Identification</b>	
A. Ignition	Ignite potassium lactate solution to an ash. The ash is alkaline, and an effervescence occurs when acid is added
B. Colour reaction	Overlay 2 ml of potassium lactate solution on 5 ml of a 1 in 100 solution of catechol in sulphuric acid. A deep red colour is produced at the zone of contact
C. Positive tests for potassium and for lactate	
<b>Purity</b>	
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Acidity	Dissolve 1 g of potassium lactate solution in 20 ml of water, add 3 drops of phenolphthalein TS and titrate with 0,1 N sodium hydroxide. Not more than 0,2 ml should be required
Reducing substances	Potassium lactate solution shall not cause any reduction of Fehling's solution
<i>Note:</i>	
This specification refers to a 60% aqueous solution	

**E 327 CALCIUM LACTATE****Definition**

<i>Chemical name</i>	Calcium dilactate Calcium dilactate hydrate 2-Hydroxypropanoic acid calcium salt
<b>Einecs</b>	212-406-7
<i>Chemical formula</i>	(C <sub>3</sub> H <sub>5</sub> O <sub>3</sub> ) <sub>2</sub> Ca·nH <sub>2</sub> O (n = 0—5)
<i>Molecular weight</i>	218,22 (anhydrous)
<i>Assay</i>	Content not less than 98% on the anhydrous basis
<i>Description</i>	Almost odourless, white crystalline powder or granules
<b>Identification</b>	
A. Positive tests for lactate and for calcium	
B. Solubility tests	Soluble in water and practically insoluble in ethanol



**Purity**

Loss on drying	Determined by drying at 120°C for four hours: — anhydrous: not more than 3,0 % — with 1 molecule of water: not more than 8,0 % — with 3 molecules of water: not more than 20,0 % — with 4,5 molecules of water: not more than 27,0 %
Acidity	Not more than 0,5 % of the dry matter expressed as lactic acid
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
pH of a 5 % solution	Between 6,0 and 8,0
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Reducing substances	No reduction of Fehling's solution

**E 330 CITRIC ACID****Definition**

<i>Chemical name</i>	Citric acid 2-Hydroxy-1,2,3-propanetricarboxylic acid $\beta$ -Hydroxytricarballic acid
<b>Einecs</b>	201-069-1
<i>Chemical formula</i>	(a) $C_6H_8O_7$ (anhydrous) (b) $C_6H_8O_7 \cdot H_2O$ (monohydrate)
<i>Molecular weight</i>	(a) 192,13 (anhydrous) (b) 210,15 (monohydrate)
<i>Assay</i>	Citric acid may be anhydrous or it may contain 1 molecule of water. Citric acid contains not less than 99,5 % of $C_6H_8O_7$ , calculated on the anhydrous basis
<i>Description</i>	Citric acid is a white or colourless, odourless, crystalline solid, having a strongly acid taste. The monohydrate effloresces in dry air

**Identification**

A. Solubility tests	Very soluble in water; freely soluble in ethanol; soluble in ether
---------------------	--

**Purity**

Water content	Anhydrous citric acid contains not more than 0,5 % water; citric acid monohydrate contains not more than 8,8 % water (Karl Fischer method)
Sulphated ash	Not more than 0,05 % after calcination at $800 \pm 25^\circ C$
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

Heavy metals (as Pb)	Not more than 5 mg/kg
Oxalates	Not more than 100 mg/kg, expressed as oxalic acid, after drying
Readily carbonizable substances	Heat 1 g of powdered sample with 10 ml of 98 % minimum sulphuric acid in a water bath at 90°C in the dark for one hour. Not more than a pale brown colour should be produced (Matching Fluid K)

## E 331 (i) MONOSODIUM CITRATE

<b>Synonyms</b>	Monosodium citrate Monobasic sodium citrate
<b>Definition</b>	
<i>Chemical name</i>	Monosodium citrate Monosodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid
<i>Chemical formula</i>	(a) $C_6H_7O_7Na$ (anhydrous) (b) $C_6H_7O_7Na \cdot H_2O$ (monohydrate)
<i>Molecular weight</i>	(a) 214,11 (anhydrous) (b) 232,23 (monohydrate)
<i>Assay</i>	Content not less than 99 % on the anhydrous basis
<i>Description</i>	Crystalline white powder or colourless crystals
<b>Identification</b>	
A. Positive tests for citrate and for sodium	
<b>Purity</b>	
Loss on drying	Determined by drying at 180°C for four hours: — anhydrous: not more than 1,0 % — monohydrate: not more than 8,8 %
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 1 % aqueous solution	Between 3,5 and 3,8
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

## E 331 (ii) DISODIUM CITRATE

<b>Synonyms</b>	Disodium citrate Dibasic sodium citrate
<b>Definition</b>	
<i>Chemical name</i>	Disodium citrate Disodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Disodium salt of citric acid with 1,5 molecules of water

<b>Einecs</b>	205-623-3
<i>Chemical formula</i>	$C_6H_6O_7Na_2 \cdot 1,5H_2O$
<i>Molecular weight</i>	263,11
<i>Assay</i>	Content not less than 99 % on the anhydrous basis
<i>Description</i>	Crystalline white powder or colourless crystals
<b>Identification</b>	
A. Positive tests for citrate and for sodium	
<b>Purity</b>	
Loss on drying	Not more than 13,0 % by drying at 180 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 1 % aqueous solution	Between 4,9 and 5,2
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg
<b>E 331 (iii) TRISODIUM CITRATE</b>	
<b>Synonyms</b>	Trisodium citrate Tribasic sodium citrate
<b>Definition</b>	
<i>Chemical name</i>	Trisodium citrate Trisodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Trisodium salt of citric acid, in anhydrous, dihydrate or pentahydrate form
<b>Einecs</b>	200-675-3
<i>Chemical formula</i>	Anhydrous: $C_6H_5O_7Na_3$ Hydrated: $C_6H_5O_7Na_3 \cdot nH_2O$ (n = 2 or 5)
<i>Molecular weight</i>	258,07 (anhydrous)
<i>Assay</i>	Not less than 99 % on the anhydrous basis
<i>Description</i>	Crystalline white powder or colourless crystals
<b>Identification</b>	
A. Positive tests for citrate and for sodium	

**Purity**

Loss on drying	Determined by drying at 180°C for four hours: — anhydrous: not more than 1,0 % — dihydrate: not more than 13,5 % — pentahydrate: not more than 30,3 %
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 5 % aqueous solution	Between 7,5 and 9,0
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

**E 332 (i) MONOPOTASSIUM CITRATE****Synonyms**

Monopotassium citrate  
Monobasic potassium citrate

**Definition**

<i>Chemical name</i>	Monopotassium citrate Monopotassium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Anhydrous monopotassium salt of citric acid
<i>Einecs</i>	212-753-4
<i>Chemical formula</i>	$C_6H_7O_7K$
<i>Molecular weight</i>	230,21
<i>Assay</i>	Content not less than 99 % on the anhydrous basis
<i>Description</i>	White, hygroscopic, granular powder or transparent crystals

**Identification**

A. Positive tests for citrate and for potassium

**Purity**

Loss on drying	Not more than 1,0 % determined by drying at 180°C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 1 % aqueous solution	Between 3,5 and 3,8
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

## E 332 (ii) TRIPOTASSIUM CITRATE

<b>Synonyms</b>	Tripotassium citrate Tribasic potassium citrate
<b>Definition</b>	
<i>Chemical name</i>	Tripotassium citrate Tripotassium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Monohydrated tripotassium salt of citric acid
<b>Einecs</b>	212-755-5
<i>Chemical formula</i>	$C_6H_5O_7K_3 \cdot H_2O$
<i>Molecular weight</i>	324,42
<i>Assay</i>	Content not less than 99% on the anhydrous basis
<i>Description</i>	White, hygroscopic, granular powder or transparent crystals
<b>Identification</b>	
A. Positive tests for citrate and for potassium	
<b>Purity</b>	
Loss on drying	Not more than 6,0% determined by drying at 180°C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 5% aqueous solution	Between 7,5 and 9,0
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

## E 333 (i) MONOCALCIUM CITRATE

<b>Synonyms</b>	Monocalcium citrate Monobasic calcium citrate
<b>Definition</b>	
<i>Chemical name</i>	Monocalcium citrate Monocalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Monohydrate monocalcium salt of citric acid
<i>Chemical formula</i>	$(C_6H_7O_7)_2Ca \cdot H_2O$
<i>Molecular weight</i>	440,32
<i>Assay</i>	Content not less than 97,5% on the anhydrous basis
<i>Description</i>	Fine white powder
<b>Identification</b>	
A. Positive tests for citrate and for calcium	

**Purity**

Loss on drying	Not more than 7,0 % determined by drying at 180 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 1 % aqueous solution	Between 3,2 and 3,5
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg
Carbonates	Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles

**E 333 (ii) DICALCIUM CITRATE****Synonyms**

Dicalcium citrate  
Dibasic calcium citrate

**Definition**

<i>Chemical name</i>	Dicalcium citrate Dicalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Trihydrated dicalcium salt of citric acid
<i>Chemical formula</i>	$(C_6H_7O_7)_2Ca_2 \cdot 3H_2O$
<i>Molecular weight</i>	530,42
<i>Assay</i>	Not less than 97,5 % on the anhydrous basis
<i>Description</i>	Fine white powder

**Identification**

A. Positive tests for citrate and for calcium

**Purity**

Loss on drying	Not more than 20,0 % determined by drying at 180 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg
Carbonates	Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles

## E 333 (iii) TRICALCIUM CITRATE

<b>Synonyms</b>	Tricalcium citrate Tribasic calcium citrate
<b>Definition</b>	
<i>Chemical name</i>	Tricalcium citrate Tricalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Tetrahydrated tricalcium salt of citric acid
<b>Einecs</b>	212-391-7
<i>Chemical formula</i>	$(C_6H_6O_7)_2Ca_3 \cdot 4H_2O$
<i>Molecular weight</i>	570,51
<i>Assay</i>	Not less than 97,5% on the anhydrous basis
<i>Description</i>	Fine white powder
<b>Identification</b>	
A. Positive tests for citrate and for calcium	
<b>Purity</b>	
Loss on drying	Not more than 14,0% determined by drying at 180°C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg
Carbonates	Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles

## E 334 L(+)-TARTARIC ACID

<b>Definition</b>	
<i>Chemical name</i>	L-tartaric acid L-2,3-dihydroxybutanedioic acid d- $\alpha$ , $\beta$ -dihydroxysuccinic acid
<b>Einecs</b>	201-766-0
<i>Chemical formula</i>	$C_4H_6O_6$
<i>Molecular weight</i>	150,09
<i>Assay</i>	Content not less than 99,5% on the anhydrous basis
<i>Description</i>	Colourless or translucent crystalline solid or white crystalline powder

**Identification**

- |                               |                           |
|-------------------------------|---------------------------|
| A. Melting range              | Between 168 °C and 170 °C |
| B. Positive test for tartrate |                           |

**Purity**

- |  |  |
|--|--|
| Loss on drying   | Not more than 0,5 % (over P <sub>2</sub> O <sub>5</sub> , three hours) |
| Sulphated ash  | Not more than 1 000 mg/kg after calcination at 800 ± 25 °C             |
| Specific optical rotation of a 20 % w/v aqueous solution | [α] <sub>D</sub> <sup>20</sup> between +11,5° and +13,5°               |
| Lead   | Not more than 5 mg/kg  |
| Mercury  | Not more than 1 mg/kg  |
| Heavy metals (as Pb)                                     | Not more than 10 mg/kg   |
| Oxalates   | Not more than 100 mg/kg expressed as oxalic acid, after drying         |

**E 335 (i) MONOSODIUM TARTRATE****Synonyms**

Monosodium salt of L-(+)-tartaric acid

**Definition**

- |                         |   |
|-------------------------|---|
| <i>Chemical name</i>    | Monosodium salt of L-2,3-dihydroxybutanedioic acid<br>Monohydrated monosodium salt of L-(+)-tartaric acid |
| <i>Chemical formula</i> | C <sub>4</sub> H <sub>5</sub> O <sub>6</sub> Na·H <sub>2</sub> O  |
| <i>Molecular weight</i> | 194,05  |
| <i>Assay</i>            | Content not less than 99 % on the anhydrous basis   |
| <i>Description</i>      | Transparent colourless crystals   |

**Identification**

- |   |  |
|---|--|
| A. Positive tests for tartrate and for sodium |  |
|---|--|

**Purity**

- |                      |  |
|----------------------|--|
| Loss on drying       | Not more than 10,0 % determined by drying at 105 °C for four hours |
| Oxalates             | Not more than 100 mg/kg expressed as oxalic acid, after drying     |
| Arsenic              | Not more than 3 mg/kg  |
| Lead                 | Not more than 5 mg/kg  |
| Mercury              | Not more than 1 mg/kg  |
| Heavy metals (as Pb) | Not more than 10 mg/kg   |



## E 335 (ii) DISODIUM TARTRATE

## Definition

*Chemical name*

Disodium L-tartrate  
 Disodium (+)-tartrate  
 Disodium (+)-2,3-dihydroxybutanedioic acid  
 Dihydrated disodium salt of L-(+)-tartaric acid

## Einecs

212-773-3

*Chemical formula* $C_4H_4O_6Na_2 \cdot 2H_2O$ *Molecular weight*

230,8

## Assay

Content not less than 99 % on the anhydrous basis

*Description*

Transparent, colourless crystals

## Identification

A. Positive tests for tartrate and for sodium

B. Solubility tests

1 gram is insoluble in 3 ml of water. Insoluble in ethanol

## Purity

Loss on drying

Not more than 17,0 % determined by drying at 150 °C for four hours

Oxalates

Not more than 100 mg/kg expressed as oxalic acid, after drying

pH of a 1 % aqueous solution

Between 7,0 and 7,5

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 mg/kg

## E 336 (i) MONOPOTASSIUM TARTRATE

## Synonyms

Monobasic potassium tartrate

## Definition

*Chemical name*

Anhydrous monopotassium salt of L-(+)-tartaric acid  
 Monopotassium salt of L-2,3-dihydroxybutanedioic acid

*Chemical formula* $C_4H_5O_6K$ *Molecular weight*

188,16

## Assay

Content not less than 98 % on the anhydrous basis

*Description*

White crystalline or granulated powder

**Identification**

A. Positive tests for tartrate and for potassium

B. Melting point

230°C

**Purity**

pH of a 1 % aqueous solution

3,4

Loss on drying

Not more than 1,0 % determined by drying at 105°C for four hours

Oxalates

Not more than 100 mg/kg expressed as oxalic acid, after drying

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 mg/kg

**E 336 (ii) DIPOTASSIUM TARTRATE****Synonyms**

Dibasic potassium tartrate

**Definition***Chemical name*Dipotassium salt of L-2,3-dihydroxybutanedioic acid  
Dipotassium salt with half a molecule of water of L-(+)-tartaric acid*Einecs*

213-067-8

*Chemical formula* $C_4H_4O_6K_2 \cdot \frac{1}{2}H_2O$ *Molecular weight*

235,2

*Assay*

Content not less than 99 % on the anhydrous basis

*Description*

White crystalline or granulated powder

**Identification**

A. Positive tests for tartrate and for potassium

**Purity**

pH of a 1 % aqueous solution

Between 7,0 and 9,0

Loss on drying

Not more than 4,0 % determined by drying at 150°C for four hours

Oxalates

Not more than 100 mg/kg expressed as oxalic acid, after drying

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 mg/kg

## E 337 POTASSIUM SODIUM TARTRATE

<b>Synonyms</b>	Potassium sodium L-(+)-tartrate Rochelle salt Seignette salt
<b>Definition</b>	
<i>Chemical name</i>	Potassium sodium salt of L-2,3-dihydroxybutanedioic acid Potassium sodium L-(+)-tartrate
<b>Einecs</b>	206-156-8
<i>Chemical formula</i>	$C_4H_4O_6KNa \cdot 4H_2O$
<i>Molecular weight</i>	282,23
<i>Assay</i>	Content not less than 99 % on the anhydrous basis
<i>Description</i>	Colourless crystals or white crystalline powder
<b>Identification</b>	
A. Positive tests for tartrate, for potassium and for sodium	
B. Solubility tests	1 gram is soluble in 1 ml of water, insoluble in ethanol
C. Melting range	Between 70 and 80 °C
<b>Purity</b>	
Loss on drying	Not more than 26,0 % and not less than 21,0 % determined by drying at 150 °C for three hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of 1 % aqueous solution	Between 6,5 and 8,5
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 338 PHOSPHORIC ACID

<b>Synonyms</b>	Orthophosphoric acid Monophosphoric acid
<b>Definition</b>	
<i>Chemical name</i>	Phosphoric acid
<b>Einecs</b>	231-633-2
<i>Chemical formula</i>	$H_3PO_4$
<i>Molecular weight</i>	98,00
<i>Assay</i>	Content not less than 71 % and not more than 83 %
<i>Description</i>	Clear, colourless, viscous liquid

**Identification**

A. Positive tests for acid and for phosphate

**Purity**

Volatile acids	Not more than 10 mg/kg (as acetic acid)
Chlorides	Not more than 200 mg/kg (expressed as chlorine)
Nitrates	Not more than 5 mg/kg (as NaNO <sub>3</sub> )
Sulphates	Not more than 1 500 mg/kg (as CaSO <sub>4</sub> )
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

*Note:*

This specification refers to a 75% aqueous solution

**E 339 (i) MONOSODIUM PHOSPHATE****Synonyms**

Monosodium monophosphate  
Acid monosodium monophosphate  
Monosodium orthophosphate  
Monobasic sodium phosphate

**Definition**

*Chemical name* Sodium dihydrogen monophosphate

*Einecs* 231-449-2

*Chemical formula*

Anhydrous:	NaH <sub>2</sub> PO <sub>4</sub>
Monohydrate:	NaH <sub>2</sub> PO <sub>4</sub> ·H <sub>2</sub> O
Dihydrate:	NaH <sub>2</sub> PO <sub>4</sub> ·2H <sub>2</sub> O

*Molecular weight*

Anhydrous:	119,98
Monohydrate:	138,00
Dihydrate:	156,01

*Assay* After drying at 6,0°C for one hour and then at 105°C for four hours, contains not less than 97% of NaH<sub>2</sub>PO<sub>4</sub>

*Description* A white odourless, slightly deliquescent powder, crystals or granules

**Identification**

A. Positive tests for sodium and for phosphate

B. Solubility tests Freely soluble in water. Insoluble in ethanol, ether or chloroform

C. P<sub>2</sub>O<sub>5</sub> content Between 58,0% and 60,0%

<b>Purity</b>	
Loss on drying	The anhydrous salt loses no more than 2,0 %, the monohydrate no more than 15,0 %, and the dihydrate no more than 25 % when dried first at 60 °C for one hour, then at 105 °C for four hours
Water-insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
pH of a 1 % aqueous solution	Between 4,1 and 5,0
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 339 (ii) DISODIUM PHOSPHATE

<b>Synonyms</b>	Disodium monophosphate Secondary sodium phosphate Disodium orthophosphate Acid disodium phosphate
<b>Definition</b>	
<i>Chemical name</i>	Disodium hydrogen monophosphate Disodium hydrogen orthophosphate
<b>Einecs</b>	231-448-7
<i>Chemical formula</i>	Anhydrous: $\text{Na}_2\text{HPO}_4$ Hydrated: $\text{Na}_2\text{HPO}_4 \cdot n\text{H}_2\text{O}$ (n = 2, 7 or 12)
<i>Molecular weight</i>	141,98 (anhydrous)
<i>Assay</i>	After drying at 40 °C for three hours and subsequently at 105 °C for five hours, contains not less than 98 % of $\text{Na}_2\text{HPO}_4$
<i>Description</i>	Anhydrous disodium hydrogen phosphate is a white, hygroscopic, odourless powder. Hydrated forms available include the dihydrate: a white crystalline, odourless solid; the heptahydrate: white, odourless, efflorescent crystals or granular powder; and the dodecahydrate: white, efflorescent, odourless powder or crystals
<b>Identification</b>	
A. Positive tests for sodium and for phosphate	
B. Solubility tests	Freely soluble in water. Insoluble in ethanol
C. $\text{P}_2\text{O}_5$ content	Between 49 % and 51 % (anhydrous)
<b>Purity</b>	
Loss on drying	When dried at 40 °C for three hours and then at 105 °C for five hours, the losses in weight are as follows: anhydrous not more than 5,0 %, dihydrate not more than 22,0 %, heptahydrate not more than 50,0 %, dodecahydrate not more than 61,0 %

Water-insoluble substances	Not more than 0,2% on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
pH of a 1,0% aqueous solution	Between 8,4 and 9,6
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 339 (iii) TRISODIUM PHOSPHATE

<b>Synonyms</b>	Sodium phosphate Tribasic sodium phosphate Trisodium orthophosphate
<b>Definition</b>	
<i>Chemical name</i>	Trisodium monophosphate Trisodium phosphate Trisodium orthophosphate
<b>Einecs</b>	231-509-8
<i>Chemical formula</i>	Anhydrous: $\text{Na}_3\text{PO}_4$ Hydrated: $\text{Na}_3\text{PO}_4 \cdot n\text{H}_2\text{O}$ (n = 0,5, 1 or 12)
<i>Molecular weight</i>	163,94 (anhydrous)
<i>Assay</i>	Sodium phosphate anhydrous, and also the hemi- and monohydrates, contains not less than 97,0% of $\text{Na}_3\text{PO}_4$ , calculated on the dried basis. Sodium phosphate dodecahydrate contains not less than 92,0% of $\text{Na}_3\text{PO}_4$ , calculated on the ignited basis
<i>Description</i>	White odourless crystals, granules or a crystalline powder. Hydrated forms available include hemi- and monohydrates, hexahydrate, octahydrate, decahydrate and dodecahydrate. The dodecahydrate contains $\frac{1}{4}$ molecule of sodium hydroxide
<b>Identification</b>	
A. Positive tests for sodium and for phosphate	
B. Solubility tests	Freely soluble in water. Insoluble in ethanol
C. $\text{P}_2\text{O}_5$ content	Between 40,5% and 43,5% (anhydrous)
<b>Purity</b>	
Loss on ignition	When dried at 120°C for two hours and then ignited at about 800°C for 30 minutes, the losses in weight are as follows: anhydrous not more than 2,0%, monohydrate: not more than 11,0%, dodecahydrate: between 45,0% and 58,0%
Water-insoluble substances	Not more than 0,2% on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)

pH of a 1,0% aqueous solution	Between 11,5 and 12,5
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 340 (i) MONOPOTASSIUM PHOSPHATE

## Synonyms

Monobasic potassium phosphate  
 Monopotassium monophosphate  
 Potassium acid phosphate  
 Potassium orthophosphate

## Definition

*Chemical name*

Potassium dihydrogen phosphate  
 Monopotassium dihydrogen orthophosphate  
 Monopotassium dihydrogen monophosphate

## Eincss

231-913-4

*Chemical formula* $\text{KH}_2\text{PO}_4$ *Molecular weight*

136,09

## Assay

Content not less than 98,0% after drying at 105 °C for four hours

*Description*

Odourless, colourless crystals or white granular or crystalline powder, hygroscopic

## Identification

- A. Positive tests for potassium and for phosphate
- B. Solubility tests
- C.  $\text{P}_2\text{O}_5$  content

Freely soluble in water. Insoluble in ethanol

Between 51,0% and 53,0%

## Purity

## Loss on drying

Not more than 2,0% determined by drying at 105 °C for four hours

## Water-insoluble substances

Not more than 0,2% on the anhydrous basis

## Fluoride

Not more than 10 mg/kg (expressed as fluorine)

## pH of a 1% aqueous solution

Between 4,2 and 4,8

## Arsenic

Not more than 3 mg/kg

## Lead

Not more than 5 mg/kg

## Mercury

Not more than 1 mg/kg

## Heavy metals (as Pb)

Not more than 10 mg/kg

## E 340 (ii) DIPOTASSIUM PHOSPHATE

**Synonyms**

Dipotassium monophosphate  
 Secondary potassium phosphate  
 Dipotassium acid phosphate  
 Dipotassium orthophosphate  
 Dibasic potassium phosphate

**Definition***Chemical name*

Dipotassium hydrogen monophosphate  
 Dipotassium hydrogen phosphate  
 Dipotassium hydrogen orthophosphate

**Einecs**

231-834-5

*Chemical formula* $K_2HPO_4$ *Molecular weight*

174,18

*Assay*

Content not less than 98 % after drying at 105 °C for four hours

*Description*

Colourless or white granular powder, crystals or masses; deliquescent substance

**Identification**

A. Positive tests for potassium and for phosphate

B. Solubility tests

Freely soluble in water. Insoluble in ethanol

C.  $P_2O_5$  content

Between 40,3 % and 41,5 %

**Purity**

Loss on drying

Not more than 2,0 % determined by drying at 105 °C for four hours

Water-insoluble substances

Not more than 0,2 % on the anhydrous basis

Fluoride

Not more than 10 mg/kg (expressed as fluorine)

pH of a 1 % aqueous solution

Between 8,7 and 9,4

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 mg/kg

## E 340 (iii) TRIPOTASSIUM PHOSPHATE

**Synonyms**

Potassium phosphate  
 Tribasic potassium phosphate  
 Tripotassium orthophosphate

**Definition***Chemical name*

Tripotassium monophosphate  
 Tripotassium phosphate  
 Tripotassium orthophosphate



<b>Einecs</b>	231-907-1
<i>Chemical formula</i>	Anhydrous: $K_3PO_4$ Hydrated: $K_3PO_4 \cdot nH_2O$ (n = 1 or 3)
<i>Molecular weight</i>	212,27 (anhydrous)
<i>Assay</i>	Content not less than 97% calculated on the ignited basis
<i>Description</i>	Colourless or white, odourless hygroscopic crystals or granules. Hydrated forms available include the monohydrate and trihydrate
<b>Identification</b>	
A. Positive tests for potassium and for phosphate	
B. Solubility tests	Freely soluble in water. Insoluble in ethanol
C. $P_2O_5$ content	Between 30,5% and 33,0% (anhydrous on ignited basis)
<b>Purity</b>	
Loss on ignition	Anhydrous: not more than 3,0%; hydrated: not more than 23,0%. Determined by drying at 105°C for one hour and then ignite at about 800°C $\pm$ 25°C for 30 minutes
Water-insoluble substances	Not more than 0,2% on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
pH of a 1% aqueous solution	Between 11,5 and 12,3
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 341 (i) MONOCALCIUM PHOSPHATE**

<b>Synonyms</b>	Monobasic calcium phosphate Monocalcium orthophosphate
<b>Definition</b>	
<i>Chemical name</i>	Calcium dihydrogen phosphate
<b>Einecs</b>	231-837-1
<i>Chemical formula</i>	Anhydrous: $Ca(H_2PO_4)_2$ Monohydrate: $Ca(H_2PO_4)_2 \cdot H_2O$
<i>Molecular weight</i>	234,05 (anhydrous) 252,08 (monohydrate)
<i>Assay</i>	Content not less than 95% on the dried basis
<i>Description</i>	Granular powder or white, deliquescent crystals or granules

**Identification**

- A. Positive tests for calcium and for phosphate
- B. P<sub>2</sub>O<sub>5</sub> content
- C. CaO content

Between 55,5 % and 61,1 % (anhydrous)

Between 23,0 % and 27,5 % (anhydrous)  
Between 19,0 % and 24,8 % (monohydrate)

**Purity**

- Loss on drying
- Loss on ignition
- Fluoride
- Arsenic
- Lead
- Mercury
- Heavy metals (as Pb)

Not less than 14 % determined by drying at 105 °C for four hours (anhydrous)

Not more than 17,5 % determined by drying at 60 °C for one hour, then at 105 °C for four hours (monohydrate)

Not more than 17,5 % after ignition at 800 °C ± 25 °C for 30 minutes (anhydrous)

Not more than 25,0 % determined by drying at 105 °C for one hour, then ignite at 800 °C ± 25 °C for 30 minutes (monohydrate)

Not more than 30 mg/kg (expressed as fluorine)

Not more than 3 mg/kg

Not more than 5 mg/kg

Not more than 1 mg/kg

Not more than 10 mg/kg

**E 341 (ii) DICALCIUM PHOSPHATE****Synonyms**

Dibasic calcium phosphate  
Dicalcium orthophosphate

**Definition***Chemical name*

Calcium monohydrogen phosphate  
Calcium hydrogen orthophosphate  
Secondary calcium phosphate

**Einecs**

231-826-1

*Chemical formula*

Anhydrous: CaHPO<sub>4</sub>  
Dihydrate: CaHPO<sub>4</sub>·2H<sub>2</sub>O

*Molecular weight*

136,06 (anhydrous)  
172,09 (dihydrate)

*Assay*

Dicalcium phosphate, after drying at 200 °C for three hours, contains not less than 98 % and not more than the equivalent of 102 % of CaHPO<sub>4</sub>

*Description*

White crystals or granules, granular powder or powder

**Identification**

- A. Positive tests for calcium and for phosphate
- B. Solubility tests
- C. P<sub>2</sub>O<sub>5</sub> content

Sparingly soluble in water. Insoluble in ethanol

Between 50,0 % and 52,5 % (anhydrous)

<b>Purity</b>	
Loss on ignition	Not more than 8,5 % (anhydrous), or 26,5 % (dihydrate) after ignition at 800°C ±25°C for 30 minutes
Fluoride	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**E 341 (iii) TRICALCIUM PHOSPHATE**

<b>Synonyms</b>	Calcium phosphate, tribasic Calcium orthophosphate
<b>Definition</b>	
<i>Chemical name</i>	Tricalcium monophosphate
<b>Einecs</b>	231-840-8
<i>Chemical formula</i>	Ca <sub>3</sub> (PO <sub>4</sub> ) <sub>2</sub>
<i>Molecular weight</i>	310,17
<i>Assay</i>	Not less than 90 % calculated on the ignited basis
<i>Description</i>	A white, odourless and tasteless powder which is stable in air
<b>Identification</b>	
A. Positive tests for calcium and for phosphate	
B. Solubility tests	Practically insoluble in water; insoluble in ethanol, soluble in dilute hydrochloric and nitric acid
C. P <sub>2</sub> O <sub>5</sub> content	Between 38,5 % and 48,0 % (anhydrous)
<b>Purity</b>	
Loss on ignition	Not more than 8 % after ignition at 800°C ±25°C, to constant weight
Fluoride	Not more than 50 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 385 CALCIUM DISODIUM ETHYLENEDIAMINETETRAACETATE

<b>Synonyms</b>	Calcium disodium EDTA Calcium disodium edetate
<b>Definition</b>	
<i>Chemical name</i>	N,N'-1,2-Ethanediybis [N-(carboxymethyl)-glycinate] [(4-)-O',O',O <sup>N</sup> ,O <sup>N</sup> ]calciate(2)-disodium Calcium disodium ethylenediaminetetra acetate Calcium disodium (ethylenedinitrilo)tetra acetate
<b>Einecs</b>	200-529-9
<i>Chemical formula</i>	C <sub>10</sub> H <sub>12</sub> O <sub>8</sub> CaN <sub>2</sub> Na <sub>2</sub> ·2H <sub>2</sub> O
<i>Molecular weight</i>	410,31
<i>Assay</i>	Content not less than 97 % on the anhydrous basis
<i>Description</i>	White, odourless crystalline granules or white to nearly white powder, slightly hygroscopic
<b>Identification</b>	
A. Positive tests for sodium and for calcium	
B. Chelating activity to metal ions positive	
C. pH of a 1 % solution between 6,5 and 7,5	
<b>Purity</b>	
Water content	5 to 13 % (Karl Fischer method)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 1105 LYSOZYME

<b>Synonyms</b>	Lysozyme hydrochloride Muramidase
<b>Definition</b>	
<i>Chemical name</i>	Enzyme Commission (EC) No: 3.2.1.17
<b>Einecs</b>	232-620-4

<i>Molecular weight</i>	About 14 000
<i>Assay</i>	Content not less than 950 mg/g on the anhydrous basis
<i>Description</i>	White, odourless powder having a slightly sweet taste
<b>Identification</b>	
A. Isoelectric point 10,7	
B. pH of a 2% aqueous solution between 3,0 and 3,6	
C. Absorption maximum of an aqueous solution (25 mg/100 ml) at 281 nm, a minimum at 252 nm	
<b>Purity</b>	
Water content	Not more than 6,0% (Karl Fischer method) (powder form only)
Residue on ignition	Not more than 1,5%
Nitrogen	Not less than 16,8% and not more than 17,8%
Arsenic	Not more than 1 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
<b>Microbiological criteria</b>	
Total bacterial count	Not more than $5 \times 10^4$ col/g
<i>Salmonellae</i>	Absent in 25 g
<i>Staphylococcus aureus</i>	Absent in 1 g
<i>Escherichia coli</i>	Absent in 1 g